

Guideline for the use of nebulised colistimethate, tobramycin and gentamicin for patients with non-cystic fibrosis bronchiectasis colonised with *Pseudomonas aeruginosa*

This guidance does not override the individual responsibility of health professionals to make appropriate decision according to the circumstances of the individual patient in consultation with the patient and /or carer. Health care professionals must be prepared to justify any deviation from this guidance.

Introduction

The purpose of this document is to guide the safe prescribing, administration and monitoring of nebulised colistimethate, tobramycin and gentamicin in adults with chronic lung infections in non-cystic fibrosis bronchiectasis with *Pseudomonas aeruginosa* colonisation. Treatment will be initiated and ongoing reviews conducted in secondary care.

This guideline is for use by the following staff groups :

Respiratory Consultants, Respiratory Nurse Specialists, Respiratory Pharmacists

Lead Clinician(s)

Millie Harris	Lead Pharmacist Respiratory
Jane Newport	Lead Practitioner Respiratory

Approved by Respiratory directorate committee on:	19/06/24
Approved by Medicines Safety Committee on: <i>Where medicines included in guideline</i>	09/04/2025
Review Date:	09/04/2028
This is the most current document and should be used until a revised version is in place	

Key amendments to this guideline

Date	Amendment	Approved by:

Background

The targeted delivery of nebulised antibiotics offers a real therapeutic option in patients with bronchiectasis by reducing bacterial burden, associated inflammation, limiting symptoms and improving quality of life. *Pseudomonas aeruginosa* is a pathogen that can cause severe lung damage in patients who become colonised and then chronically infected. Patients with non-cystic fibrosis (CF) bronchiectasis are at risk of significant morbidity and mortality from the damage caused by the pathogen.

Nebulised antipseudomonal antibiotic treatment has been shown to improve lung function, slow the rate of respiratory decline and reduce the frequency of exacerbations. Nebulised antibiotics are able to achieve high local concentrations with low systemic absorption and toxicity as opposed to intravenous antibiotics where there is a high risk of developing adverse effects from systemic absorption. The British Thoracic Society guideline for bronchiectasis treatment in adults recommends considering long term nebulised antibiotics for those who experience **three or more exacerbations per year**. Nebulised colistimethate is considered first line therapy, however gentamicin or tobramycin may be considered as second line (BTS, Dec 2018).

Areas of Prescribing Responsibility

Joint Responsibilities of All Clinicians Involved in Patient Care	
Ensure optimal pharmacological and non-pharmacological treatment prior to commencing nebulised antibiotics, which may include: <ul style="list-style-type: none"> • Smoking cessation advice and signposting for support. • Encouraging regular chest clearance, such as active cycle of breathing techniques and consider mucolytic therapy. • Request sputum cultures if change in sputum colour or consistency, and prescribe antibiotics if clinically appropriate. 	
Responsibilities of Initiating Clinician	
<ul style="list-style-type: none"> • To diagnose chronic infection likely to respond to nebulised antibiotic therapy in non-CF bronchiectasis patients based on a timely and comprehensive assessment. • Discuss with the patient the intended benefits of treatment and side effects. • Refer for audiology baseline assessment for tobramycin and gentamicin therapy (see Appendix A). • Order and review baseline renal bloods on ICE. • To refer to Respiratory Nurse Specialists (RNS) for trial of medication. • Write prescription on trust medication chart for the trial dose. • Provide FP10 prescription to RNS for the first month's treatment, which should contain: <ul style="list-style-type: none"> Colistimethate: <ul style="list-style-type: none"> ○ Colistimethate solution 1 million unit or 2 million unit ○ Sodium chloride 0.9% solution for nebulisation or for injection ○ 2.5mg nebules of salbutamol twice daily prior to antibiotic nebulisation Gentamicin: <ul style="list-style-type: none"> ○ Alcohol and preservative free gentamicin 80mg/2ml injection solution e.g. Cidomycin® brand ○ Sodium chloride 0.9% solution for nebulisation or for injection ○ 2.5mg nebules of salbutamol twice daily prior to antibiotic nebulisation ○ 5ml syringe and sterile needles Tobramycin: 	

<ul style="list-style-type: none"> ○ Tobramycin 300mg/5ml ampoules 56 per 28 days ○ 2.5mg nebulises of salbutamol twice daily prior to antibiotic nebulisation • Establish appropriate blood monitoring as discussed below. • Provide patient with patient information leaflet.
Responsibilities of Respiratory Nurse Specialists
<ul style="list-style-type: none"> • Check baseline audiology assessment for tobramycin and gentamicin nebulises is completed prior to trial. • To complete hospital-based trial of medication and monitor for response and adverse drug reaction during trial. • Provide nebuliser cleaning advice as per nebuliser policy WAHT-RES-002. • To complete follow ups with patient at 2 weeks, 3 months, 6 months, 12 months and then annually. • To provide sputum pots and ensure sputum ordered on ICE for 3 and 6 months' post initiation. • To ensure annual lung function is ordered and completed by patient. • To provide the patient/carer with nebuliser system and consumables. • Ensure bloods are completed as per guidance below and at prescriber discretion. • Write a letter to the GP to share the patient's care for colistimethate when the test dose has been carried out and proven benefit has been established, note nebulised gentamicin and tobramycin are red drugs on the Herefordshire and Worcestershire Joint Formulary. • If reactions occur to medications to liaise with named consultant and GP regarding ongoing treatment options.
Patient/Carer Responsibilities
<ul style="list-style-type: none"> • To use medication as directed. • Attend virtual and face to face appointment with secondary care and primary care. • Report any adverse effects as outlined below to their GP or care provider within secondary care whilst using the nebulised antibiotics. • Take responsibility for their care and treatment and seek clarification if they have any questions regarding their condition/treatment. • Ensure they have a clear understanding of their treatment. • Correctly store and administer the nebuliser solution. • Continue with standard airways treatments. • Return all equipment if treatment is discontinued.

Guidance for prescribing

Dose

Colistimethate	<p>1 or 2 million units twice daily via nebulisation.</p> <p>Available as a licensed solution for nebulisation. Use in non-CF patients is off-label.</p> <p>Available as Colomycin® powder for injection, infusion or inhalation. Add 2-4mL of 0.9% sodium chloride, dependent on strength used, to the vial and shake gently to dissolve the powder.</p>
Tobramycin	<p>300mg twice daily via nebulisation. 28 days on, 28 days off.</p> <p>Available as a 300mg/4ml or 300mg/5ml licensed solution for nebulisation. The use of the licensed nebulised preparation for this indication is off-label. Nebulisation should take place over approximately 15 minutes.</p> <p>The use of 80-160mg twice daily using the phenol-free solution for injection via nebulisation is unlicensed and off-label. The licensed nebulised preparation should therefore be used in preference.</p>
Gentamicin	<p>80mg twice daily via nebulisation.</p> <p>The use of the intravenous preparation by nebulisation is unlicensed and off-label.</p> <p>Use a preservative-free brand such as Cidomycin®.</p> <p>2ml of gentamicin 80mg/2ml ampoules should be drawn up and mixed with 2ml of sterile 0.9% saline solution. Nebulisation should take place over approximately 15 minutes.</p>

Contra-Indications

Colistimethate	<ul style="list-style-type: none"> • Hypersensitivity to the active substance, colistin or to polymyxin B. • Patients with myasthenia gravis due to the risk of aggravating muscle weakness.
Tobramycin	<ul style="list-style-type: none"> • Hypersensitivity to tobramycin, gentamicin or other aminoglycosides. • Patients with myasthenia gravis due to the risk of aggravating muscle weakness.
Gentamicin	

Cautions

Colistimethate	<ul style="list-style-type: none"> Renal impairment. A baseline renal function should be determined prior to initiating therapy and monitored throughout treatment. There is no specified frequency for renal function monitoring from the manufacturer, so this should be decided on an individual patient basis at the discretion of the initiating clinician. Extreme caution in patients with porphyria.
Tobramycin	<ul style="list-style-type: none"> Renal impairment. A baseline renal function should be determined prior to initiating therapy and monitored throughout treatment. There is no specified frequency for renal function monitoring from the manufacturer, so this should be decided on an individual patient basis at the discretion of the initiating clinician. Systemic absorption is expected to be minimal. Pre-existing vestibular or auditory impairment. Severe, active haemoptysis. Concomitant use with potent diuretics due to the risk of nephrotoxicity, although this risk is likely to be minimal due to the local action of the nebulised antibiotic.
Gentamicin	

Pregnancy and breast-feeding

Colistimethate	<p>There is no adequate data from the use of colistimethate sodium in pregnant women. There are studies to show colistimethate sodium crosses the placental barrier so there may be a risk of foetal toxicity in repeated doses. Only use if benefit outweighs the risk.</p> <p>The drug is excreted in breastmilk so should only be used if benefit to mother outweighs the potential risk to the infant.</p>
Tobramycin	<p>There is no adequate data for the use of nebulised tobramycin in pregnant women. It is not believed to be teratogenic but may cause foetal harm such as deafness in high systemic concentrations. Use should only be considered if benefits outweigh the risks.</p> <p>Systemic tobramycin is excreted in breastmilk however it is not known if concentrations are high enough with nebulised use for this to occur. Due to the potential for ototoxicity and nephrotoxicity, a risk versus benefit decision should be made.</p>
Gentamicin	<p>Gentamicin crosses the placental barrier and due to the potential risk of inner ear and renal damage to the foetus, use in pregnancy should be avoided.</p> <p>Gentamicin is excreted in breastmilk so should only be used if benefit to mother outweighs the potential risk to the infant. Diarrhoea and fungal infection could occur in the breast-fed infant.</p>

Adverse Effects

Colistimethate	<ul style="list-style-type: none"> Coughing and bronchospasm. Sore throat/mouth which may be due to <i>Candida albicans</i> infection or hypersensitivity. Encourage to rinse mouth after use. Skin rash indicates hypersensitivity and therapy should be withdrawn. Toxicity can lead to neuromuscular blockade, causing muscular weakness, apnoea and respiratory arrest. However, there is a low risk of systemic toxicity with nebulised therapy.
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Tobramycin	<ul style="list-style-type: none"> • Coughing and bronchospasm • Ototoxicity • Nephrotoxicity
Gentamicin	

For a full list of adverse effects, please refer to the Summary of Product Characteristics:

Colistimethate: <https://www.medicines.org.uk/emc/product/1094>

Tobramycin: <https://www.medicines.org.uk/emc/product/14480/smpc>

Gentamicin: <https://www.medicines.org.uk/emc/product/14742>

Interactions

Colistimethate	The risk of drug interaction is believed to be minimal via the nebulised route, however the risk of neurotoxicity and nephrotoxicity with concomitant drugs with this potential such as aminoglycosides, diuretics or cephalosporins should be considered.
Gentamicin	There is a theoretical risk of nephrotoxicity and ototoxicity with concomitant use with other medications such as diuretics and ACEis however systemic absorption is likely to be minimal with nebulised therapy.
Tobramycin	

For a full list of interactions, please refer to the Summary of Product Characteristics:

Colistimethate: <https://www.medicines.org.uk/emc/product/1094>

Tobramycin: <https://www.medicines.org.uk/emc/product/14480/smpc>

Gentamicin: <https://www.medicines.org.uk/emc/product/14742>

Ongoing monitoring

Colistimethate	<ul style="list-style-type: none"> • Renal function. There is no specified frequency for renal function monitoring from the manufacturer, so this should be decided on an individual patient basis at the discretion of the initiating clinician. • Signs and symptoms of toxicity. Overdose can lead to neuromuscular blockade, causing muscular weakness, apnoea and respiratory arrest. • Note there is a low risk of systemic toxicity with nebulised therapy.
Tobramycin	<ul style="list-style-type: none"> • Renal function, frequency as specified by clinician overseeing care. • Assessment of ongoing auditory function, particular if patient reports tinnitus or hearing loss during therapy. • Monitoring of serum tobramycin concentrations are recommended by the manufacturer in patients with known or suspected auditory or renal dysfunction. If ototoxicity or nephrotoxicity occurs, therapy should be discontinued until serum concentration falls below 2µg/ml. However systemic absorption is likely to be low with nebulised therapy. • There is no guidance to suggest monitoring of gentamicin nebulised therapy is required however plasma levels can be considered in patient with known or suspected auditory or renal dysfunction, or if toxicity is suspected.
Gentamicin	

For more prescribing guidance, please refer to the Summary of Product Characteristics:

Colistimethate: <https://www.medicines.org.uk/emc/product/1094>

Tobramycin: <https://www.medicines.org.uk/emc/product/14480/smpc>

Gentamicin: <https://www.medicines.org.uk/emc/product/14742>

Inpatient use

If the patient is admitted for treatment of a bronchiectasis associated infection, the nebulised treatment can be stopped whilst receiving antibiotics via another route.

If the patient is to continue on the nebulised antibiotics, they need to be in a side room with a window. Staff should not enter the room for 30 minutes post nebuliser. The patient should bring in their own equipment where possible, but can temporarily be provided for inpatient use if unavailable.

Management

Hospital Trial Appointment

Pre-Trial Checks

- Check patient details and ensure positive sputum samples on Trust results system.
- Check patient's allergy status.
- Outline rationale for therapy and ongoing regime that is expected to be followed if trial is successful. Outline the potential side effects, both immediate and latent.
- Ensure patient understands need to protect family members/ carers from exposure in the home environment.
- Outline the shared care agreement for the therapy and ensure contact details are issued for the Respiratory Nurse Team who have assumed responsibility for the drug trial under a Trust thoracic consultant physician.
- Explain the nature of the trial, obtain informed consent and document.
- Take a full set of observations and ensure the patient is clinically well.
- Document if the patient has had formal chest clearance instructions by a specialist chest physiotherapist and if not, obtain consent to refer for this.

Trial

- Ensure anaphylaxis kit is available in the clinic for use in accordance with the anaphylaxis resuscitation council guidelines.
- Explain to the patient the first stage of the process and how to set up the vented mouthpiece, tube and components.
- Ask the patient/ or carer, to add the short-acting beta-2 agonist (SABA) to the nebuliser chamber to assess for dexterity and coherence and understanding, and to aid memory retention.
- Inform the patient that nebulised medication can trigger cough and reassure the patient that this is a desirable effect in order to aid chest clearance prior to the antibiotic. Ensure patient has a supply of tissues.
- Administer SABA and document the time/ lot number and expiry date and sign prescription card. Document time of administration on documentation.
- Once administration is finished and chest clearance complete ensure patient comfort.
- Explain to the patient the next stage of the trial while waiting 20 minute for optimal SABA efficacy.
- Explain to the patient how to remove the vented mouthpiece, chamber and tube and to replace with the non-vented mouthpiece with external filter including how and when to change the filter pads.
- Talk the patient/carer through the reconstitution/dilution of the nebulised antibiotic and ensure they are able to do this and to prime the chamber with the reconstituted/ diluted antibiotic.
- Ensure the patient is sitting in an upright position, 20 minutes following the SABA and ask them to perform a peak expiratory flow (PEF) three times, recording the best of three (standing is the optimal position for this, however if the administration of the antibiotic has caused the patient to become lightheaded, it is desirable to be able to keep the patient seated post-dose and have a comparable PEF).

- Seat the patient nearer to the open window and ensure call bell within reach.
- Reiterate side effects and to press the bell if any concerns/ symptoms.
- Instruct the patient to begin nebulising once clinician and carers have left the room.
- Clinician should have mask ready in case they need to re-enter the room in response to patient call bell, and for entering immediately after while drug particles are still airborne.

Post-Trial

- Immediately post administration, ask patient to take PEF and record the best of three.
- Remove patient to the second room and vacate trial room for 30 minutes allowing clearance of the airborne particles.
- Continue to closely monitor patient for cough, wheeze and retake PEF every 15 minutes or sooner as clinical presentation dictates.
- **If bronchoconstriction occurs, or patient has terminated the administration due to chest tightness, wheeze or cough, immediately administer another SABA, and call for medical attention. Take full set of observations, ensure the patient is placed supine on a couch at a minimum 45-degree angle. If any signs/ symptoms of anaphylaxis, recline patient flat immediately and seek immediate medical attention via 2222 while administering SABA back to back via oxygen and follow Trust protocol for management of anaphylaxis.**
- Once patient has completed a minimum of one hour monitoring with PEF every 15 minutes, no change or a maximum of 15% reduced/ <200mls PEF record indicates a passed trial. Reiterate to the patient signs and symptoms of latent effects such as increase in non-productive cough, chest tightness and increased breathlessness following administration which the eases by the use of an additional nebulised SABA and symptoms which wear off by the time the next dose is due. If this occurs they are to stop their nebulised antibiotic and contact the Respiratory Nurse Team.
- Drop if PEF of >15% and >200mls observe for cough, wheeze. Administer salbutamol and repeat PEF every 15 minutes until normalised and if unsure seek consultant advice.
- A drop of >15% is likely to not be for nebulised antibiotics and should be discussed with consultant.
- If the patient has passed the trial issue the patient with one-month supply of the above medication and a telephone appointment for 2 weeks.
- Issue patient with labelled sputum pots (x3) GP/ Outpatient bags and requests for Microbiology/ Culture and Sensitivity (MC&S) and advise patient to submit an early morning sputum sample the same day to their local GP before lunch time three months following the start of their regime. Subsequent samples should be sent for culture at the first sign of a chest infection.

2 Week Telephone Call

A review of:

- Medication compliance.
- Symptoms.
- Side effects.
- Exacerbation frequency.
- Chest clearance compliance.
- Ensuring patient is cleaning equipment appropriately.
- Submission of sputum samples prior to next face to face appointment.

If no concerns review in 3 months at clinic face to face. Advised if concerns regarding treatment to contact respiratory nurse team to discuss immediately.

If concerns regarding toleration of treatment, respiratory nurses to advise treatment to stop immediately. If still acutely breathless then to take additional salbutamol nebuliser. Respiratory Nurses will call patient within the week to check resolution of symptoms. Respiratory Nurses will inform consultant of non-toleration of treatment and book clinic appointment follow up to discuss next options.

3-month and 6 month Review Face to Face

A review of:

- Medication compliance.
- Symptoms.
- Side effects.
- Exacerbation frequency.
- Chest clearance compliance.
- Recent hospital admissions.
- Sputum sample results.
- Renal function, if appropriate, at interval specified by initiating clinician.
- Appropriate cleaning of equipment.

If no concerns review at planned clinic appointment. Advised if concerns regarding treatment to contact respiratory nurse team to discuss immediately.

If concerns regarding toleration of treatment, respiratory nurses to advise treatment to stop immediately. If still acutely breathless then to take additional salbutamol nebuliser. Respiratory Nurses will call patient within the week to check resolution of symptoms. Respiratory Nurses will inform consultant of non-toleration of treatment and book clinic appointment follow up to discuss next options.

12 month review and Annually thereafter

A review of:

- Medication compliance.
- Symptoms.
- Side effects.
- Exacerbation frequency.
- Chest clearance compliance.
- Recent hospital admissions.

- Sputum sample results.
- Renal function, if appropriate, at interval specified by initiating clinician.
- Appropriate cleaning of equipment.
- Supply of new equipment.
- Lung function.

If no concerns review at planned next clinic appointment. Advised if concerns regarding treatment to contact respiratory nurse team to discuss immediately.

If concerns regarding toleration of treatment, respiratory nurses to advise treatment to stop immediately. If still acutely breathless then to take additional salbutamol nebuliser. Respiratory Nurses will call patient within the week to check resolution of symptoms. Respiratory Nurses will inform consultant of non-toleration of treatment and book clinic appointment follow up to discuss next options.

Contact Details

Respiratory Advice and Guidance WRH: wah-tr.respiratoryadviceworcester@nhs.net

Respiratory Advice and Guidance ALX: wah-tr.respiratoryadviceredditch@nhs.net

Respiratory Specialist nurses WRH: ext 38757

Respiratory Specialist Nurses ALX: ext 44991

Worcestershire Acute Hospitals NHS Trust Main Switchboard: 01905 760255

Appendix A - Audiology Referral Letter

Please email the completed referral form to: wah-tr.AudiologyHearingServices@nhs.net

Referral for baseline audiology screening for patients starting tobramycin/gentamicin nebulised therapy

Patient Name:	Address:
D.O.B:	Post code:
Hospital Number:	Contact number:
Date of referral	FREQUENCY OF TESTS: Baseline

Dear Audiology Department Staff

The above patient will be starting nebulised tobramycin/gentamicin as part of their treatment for bronchiectasis with *Pseudomonas aeruginosa* infection, under the care of Dr xxxxxxx.

The consultant in charge of the patient's care would like them to have pre-treatment audiology screening as a baseline prior to commencing treatment.

We would be grateful if you could arrange for this to be done in your department.

Monitoring

Page/ Section of Key Document	Key control:	Checks to be carried out to confirm compliance with the Policy:	How often the check will be carried out:	Responsible for carrying out the check:	Results of check reported to: <i>(Responsible for also ensuring actions are developed to address any areas of non-compliance)</i>	Frequency of reporting:
	WHAT?	HOW?	WHEN?	WHO?	WHERE?	WHEN?
	Safe and effective prescribing, monitoring and administration of colistimethate, gentamicin and tobramycin nebulisers.	Review of prescribing at patient presentation.	At patient presentation to hospital (outpatient or inpatient) or flagged by primary care	Respiratory consultants, doctors, pharmacists	Inappropriate prescribing reported on Datix system	As patients present.

References

1. T Hill A, L Sullivan A, D Chalmers J, *et al*/ British Thoracic Society Guideline for bronchiectasis in adults. *Thorax* 2019;74:1-69. Available from: <https://www.brit-thoracic.org.uk/document-library/guidelines/bronchiectasis/bts-guideline-for-bronchiectasis-in-adults/> [accessed 12/4/24]
2. Summary of Product Characteristics (SmPC) for *Colomycin 1 million International Units (IU) Powder for solution for injection, infusion or inhalation*, Teva UK Limited, date of revision of text 12/07/2023, <https://www.medicines.org.uk/emc/product/1094>
3. Summary of Product Characteristics (SmPC) for Tobramycin 300 mg/5 ml Nebuliser Solution, Creo Pharma Limited, date of revision of text 09/01/2024, <https://www.medicines.org.uk/emc/product/14480/smpc>
4. Summary of Product Characteristics (SmPC) for *Cidomycin 80mg/2ml Solution for Injection*, ADVANZ Pharma, date of revision of text 18/03/2024, <https://www.medicines.org.uk/emc/product/14742>

Contribution List

Contribution List

This key document has been circulated to the following individuals for consultation;

Designation
Emma Hurst – Respiratory Nurse Specialist
Katie Brown - Respiratory Nurse Specialist
Shiji Mathews - Respiratory Nurse Specialist
Donna Hurlbutt - Respiratory Nurse Specialist
Rebecca Thomas - Respiratory Nurse Specialist
Patrycja Pucilowska - Respiratory Nurse Specialist
Dr Andrew Crawford – Respiratory Consultant

This key document has been circulated to the chair(s) of the following committee's / groups for comments;

Committee
Respiratory Directorate committee (19/6/24 and 26/03/25)
DMB (26/03/25)

Supporting Document 1 - Equality Impact Assessment Tool

. To be completed by the key document author and included as an appendix to key document when submitted to the appropriate committee for consideration and approval.

Please complete assessment form on next page;

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	Millie Harris
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Details of individuals completing this assessment	Name	Job title	e-mail contact
	Millie Harris	Lead Pharmacist Respiratory	Millie.harris@nhs.net
Date assessment completed	26/06/24		

Section 2

Activity being assessed (e.g. policy/procedure, document, service redesign, policy, strategy etc.)	Title: Guideline for the use of nebulised colistimethate, tobramycin and gentamicin for patients with non-cystic fibrosis bronchiectasis colonised with <i>Pseudomonas aeruginosa</i>			
What is the aim, purpose and/or intended outcomes of this Activity?	Provide guidance to doctors, nurses and pharmacists on the safe prescribing, administration and monitoring of nebulised colistimethate, tobramycin and gentamicin for patients with non-cystic fibrosis bronchiectasis colonised with <i>Pseudomonas aeruginosa</i>			
Who will be affected by the development & implementation of this activity?	<input type="checkbox"/> Service User <input checked="" type="checkbox"/> Patient <input type="checkbox"/> Carers <input type="checkbox"/> Visitors	<input checked="" type="checkbox"/> Staff <input type="checkbox"/> Communities <input type="checkbox"/> Other _____		
Is this:	<input checked="" type="checkbox"/> Review of an existing activity			

	<input type="checkbox"/> New activity <input type="checkbox"/> 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.	British Thoracic Society guidance Summary of Product Characteristics BNF
Summary of engagement or consultation undertaken (e.g. who and how have you engaged with, or why do you believe this is not required)	As per contribution list
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 <u>positive</u> impact	Potential <u>neutral</u> impact	Potential <u>negative</u> impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Age		<input checked="" type="checkbox"/>		
Disability		<input checked="" type="checkbox"/>		
Gender Reassignment		<input checked="" type="checkbox"/>		
Marriage & Civil Partnerships		<input checked="" type="checkbox"/>		
Pregnancy & Maternity		<input checked="" type="checkbox"/>		
Race including Traveling Communities		<input checked="" type="checkbox"/>		
Religion & Belief		<input checked="" type="checkbox"/>		
Sex		<input checked="" type="checkbox"/>		
Sexual Orientation		<input checked="" type="checkbox"/>		

Equality Group	Potential <u>positive</u> impact	Potential <u>neutral</u> impact	Potential <u>negative</u> impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Other Vulnerable and Disadvantaged Groups (e.g. carers; care leavers; homeless; Social/Economic deprivation, travelling communities etc.)		<input checked="" type="checkbox"/>		
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)		<input checked="" type="checkbox"/>		

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	Millie Harris
Date signed	6/6/24
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	No
2.	Does the implementation of this document require additional revenue	No
3.	Does the implementation of this document require additional manpower	No
4.	Does the implementation of this document release any manpower costs through a change in practice	No
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	No
	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.