

**Nurse Practitioner Clinical Protocols
for
Respiratory Medicine**

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Feb 2009

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North Metropolitan Health Service**

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North Metropolitan Health Service
Sir Charles Gairdner Hospital
Nurse Practitioner
Respiratory Medicine



CLINICAL PRACTICE PROTOCOL

MANAGEMENT OF PATIENTS WITH CYSTIC FIBROSIS WHO PRESENT WITH SYMPTOMS SUGGESTIVE OF LOWER RESPIRATORY TRACT INFECTION OR RESPIRATORY EXACERBATION

BACKGROUND INFORMATION

Cystic Fibrosis (CF) is a multi-system disease. Although respiratory disease is the major cause of morbidity and death, pancreatic function (endocrine and exocrine), liver, gut, reproductive organs and skeletal system (osteoporosis) and (arthritis), are all affected by the disease process.

The centre for the medical care of adults with CF in WA is at Sir Charles Gairdner Hospital. Most patients have previously been treated at PMH and transferred for ongoing management at SCGH about the age of leaving school.

Treatment of people with CF follows a multi-disciplinary model. The CF team includes medical staff, nurses, physiotherapist, dietitian, occupational therapist, pharmacist and social worker. At times other specialist medical staff will need to be consulted. It is important to utilize all these services for the optimum care of patients with CF.

The most frequent indication for presentation and subsequent admission is a respiratory tract exacerbation (RTE) associated with infection. Other indications can be complications of respiratory disease (haemoptysis, pneumothorax) or non respiratory complications of CF (eg GIT problems, liver disease, diabetes etc).

Respiratory tract infection is a major concern in the care of people with CF and all patients are concerned about the risk of acquiring antibiotic resistant organisms. Most patients that have an unplanned presentation at the hospital do so for an exacerbation of their lung infection. Many will require and will receive Intravenous (IV) antibiotics either on an inpatient or outpatient basis.

Intravenous access is a major consideration for people with CF and some patients have an Implanted Venous Access Device (infusaport) in situ. In the absence of an implanted device, a Peripherally Inserted Central Catheter (PICC) line is usually used. These are inserted by appropriately trained staff or by the anaesthetists in the recovery room. Less often a subclavian or internal jugular CVC line is required - usually inserted by an anaesthetist.

This protocol is confined to the assessment and management of patients likely to be discharged home early from hospital on IV antibiotics or commenced in the clinic on intravenous anti-biotics, on the Cystic Fibrosis Clinic home IV program.

The Cystic Fibrosis Standards of care, Australia (2008) recommend for home IV therapy:

- Standard 1. Home therapy may be considered for treatment of respiratory exacerbations for people with CF.
- Standard 2. Protocols for selection and training of patients, delivery of treatment and monitoring of responses are required.
- Standard 3. The first dose of parenteral antibiotic should be administered in hospital.
- Standard 4. Written information of the treatment plan and emergency contact details at the CF Centre should be provided to patients.

These standards will be incorporated into this clinical practice protocol.

Home treatment for respiratory tract exacerbations can be oral Ciprofloxacin with or without inhaled Tobramycin or Colistin. This is similar to other centres around Australia as assessed by Bell S and Bunting J.P (2005). These drugs are used when treating Pseudomonas Aeruginosa related Respiratory Tract Exacerbation.

There are some guiding principles to follow when treating Pseudomonus Aeruginosa related RTE.

1. Two antibiotics are chosen – not one. This is thought to reduce the occurrence of resistant strains of infection.
2. There are a first line of antibiotics to choose from before considering other antibiotics. This is to reduce the occurrence of resistant strains of infection. Second and then third line antibiotics are used when the first line antibiotics are no longer effective or contraindicated in the individual patient.
3. The dosage for CF patients is usually higher than the usual population due to their higher clearance rates when compared to the general population.

Tobramycin is used as a first line drug for exacerbations in Cystic Fibrosis. Our CF clinic uses once a day dosing. Once daily intravenous dosing versus multiple daily dosing was reviewed and found to be just as effective. (Smyth A.R, Bhatt J, Tan T.H, 2006)

Timentin® is also a first line agent. The dosing is higher in Cystic Fibrosis due to the higher clearance of the drug. Wang J.P, Unadkat J.D, al Habet S.M, O’Sullivan T.A, Williams-Warren J, Smith A.L, Ramsey B, (1993) demonstrated that Ticarcillin required higher doses in Cystic Fibrosis patients to reach a pre determined steady state, and as far back as 1987 de Groot R and Smith A.L in Yankaskas J.R, Marshall B.C, (2004) pointed out that “Clinicians must be aware that for many antibiotics, differences in volume of distribution and the rate of elimination in CF patients require higher doses and shorter dosing intervals.”

A Cochrane review of the literature looked at single versus combination intravenous therapy for people with Cystic Fibrosis. The review concluded that there was not evidence to draw a conclusion. (Elphick H.E, Tan A, 2005) Most CF centres use at least two antibiotics to reduce the risk of developing resistant strains of bacteria and for perceived increased effectiveness.

SCGH CF Clinic uses intravenous antibiotic treatment for severe exacerbations of chest infection in Cystic Fibrosis. A Cochrane review looked at oral treatment of Pseudomonas in people with Cystic Fibrosis compared to nebulised or intravenous treatment for exacerbations and long term treatment, there was not conclusive evidence that oral treatment was more or less effective. The study recommended more higher powered trials be run. (Remington T, Jahnke N, Harknsee C, 2007)

A number of studies have looked at the cost of home versus hospital intravenous treatment (Balaguer A, Gonzalez de Dios J, 2008) (Elliot, R.A, Thornton J, Webb A.K, DoddM, Tully M.P, 2005) (Graff von Schulenburg, J.M, Greiner W, Klettke U, Wahn U, 1997) as well as measured outcomes and it can be said that home IV therapy is effective in cost and outcome. (Donarti M. A, Guenette G, Auerbach H, 1987) (Esmond, G, Butler M, McCormack A, 2006) (Klettke, U, Magdorf K, Staab D, Bisson S, Paul K, Wahn U, 1999) (Riethmueller J, Busch A, Damm V, Ziebach R, Stern M, 2002) (Strandvik B, Hjelte L, Malmborg A-S, Widen B, 1992) (Thornton J, Elliott R.A, Tully M, Dodd M, Webb A, 2005) (Winter R.J, George R.J, Deacock s.J, Shee C.D, Geddes D.M, 1984) (Wolter J.M, Bowler S.D, Nolan P.J, McCormack J.G, 1997) Although one study cautions that close supervision is required on home IV antibiotics (Thornton J, Elliott R, Tully M, Dodd M, Webb A, 2004) and another study (Bosworth D.G, Nielson D.W, 1997) concluded home care was less effective due to longer treatment courses.

**PROTOCOL FOR THE MANAGEMENT OF PATIENTS WITH CYSTIC FIBROSIS
WHO PRESENT WITH SYMPTOMS OF A LOWER RESPIRATORY TRACT
INFECTION**

SCOPE OF PRACTICE		
PRACTITIONER	SCOPE	OUTCOMES
Nurse Practitioner – Respiratory Medicine (NPRM)	Patients with Cystic Fibrosis who present to SCGH with symptoms suggestive of Lower Respiratory Tract Infection. (LRTI)	Appropriate patients are identified and treated by the NPRM
Medical Practitioner + NPRM	Patients in respiratory failure Patients with SpO2 < 90%, a pO2 <60, and PCO2 > 50 Patients with symptoms suggestive of cardiac or acute gastric origin Patients whose condition warrants hospital admission with haemoptysis	Patients outside the NPRM scope will be referred to a Medical Practitioner
PATIENT ASSESSMENT		
PATIENT HISTORY	REQUIRED INFORMATION	OUTCOMES
Initial assessment <i>Breathlessness</i>	Observe patients for signs of dyspnoea Determine SpO2 and Respiratory Rate FEV1 Hx of Severity	Patients with SpO2 =<90% are provided with supplemental O2 and referred to a Medical Practitioner stat Measures are implemented to facilitate respiration and promote patient comfort
Symptoms suggestive of infection <i>Increased cough and sputum production ± fever ± anorexia</i>	Determine <ul style="list-style-type: none"> • nature of cough and duration • change in the amount of sputum produced • colour of sputum – purulent? • presence or absence of haemoptysis • temperature • Loss of weight and appetite. 	Changes in amount of sputum and usual cough will be considered when determining patient’s plan of care

PATIENT ASSESSMENT (cont.)		
PATIENT HISTORY	REQUIRED INFORMATION	OUTCOMES
Symptoms arising from causes other than infection	If pain present assess origin site and intensity (pain score)	
<i>Chest pain</i>	If chest pain present, consider the likelihood of cardiac origin, pneumothorax or pulmonary embolus. Consider mucous plugging or Pleurisy. For CXR	Patients reporting chest pain suggestive of cardiac origin or PE will be referred to a Medical Officer
	Offer analgesia to patient with musculo skeletal or pleuritic chest pain	Pain scores will be reduced following implementation of measures to relieve pain
<i>Abdominal pain</i>	Determine recent bowel habits Consider likelihood of sub diaphragmatic pathology or pleurisy. Consider DIOS, Pancreatitis. Amylase, ?AXR, ?US	Constipation and other causes of non respiratory origin will be eliminated as a cause of abdominal pain
Known risk factors for the presenting symptoms	Determine recent exposure to risk factors for infection: <ul style="list-style-type: none"> • Travel - esp. overseas • Contact with children • Previous transplant • Current steroid medication • Exposure to spore forming agents (potting mix etc) or air conditioning 	Exposure to relevant risk factors will be ascertained and considered with other history, signs and symptoms when considering a diagnosis
Previous medical history	Record any new information relating to medical, surgical (and obstetric) history. Record Adverse Drug reactions. (Drug, Date, severity)	
Current medications	List current medications. The source of that information, recent changes, stated compliance.	

PATIENT ASSESSMENT (cont.)		
Other relevant information	Determine any other issues (e.g. psychosocial) which may impact on treatment plan	LRTI will be recognised and a plan devised for future management with regard for previous management

PHYSICAL ASSESSMENT		
PHYSICAL ASSESSMENT	REQUIRED INFORMATION	OUTCOMES
Usual physical examination	Record findings Note whether febrile	
Lung/Respiratory assessment <i>Inspection</i>	Observe patent for: <ul style="list-style-type: none"> • Respiratory Rate • Audible grunting or wheezing • Rib retraction • Abdominal breathing • Nasal flaring • Pallor, cyanosis, clubbing • Pharyngitis 	Findings of physical assessment will be considered when determining patient's plan of care Other respiratory tract pathology – e.g. URTI, space occupying lesion, obstruction, foreign body, allergic reaction etc. will be considered as a possible cause of presenting symptoms
<i>Auscultation</i>	Auscultate the chest to determine presence of: <ul style="list-style-type: none"> • wheezing (indication of asthma, obstruction or pneumonia. • crackles- rattles heard while air passes through respiratory secretions. (Indication of bronchitis/ pneumonia) 	
<i>Percussion</i>	Percuss the chest wall to identify presence of fluid or solid tissue in the lung or pleural space.	
Gender specific assessment	Obtain a menstrual history for female patients who report haemoptysis	Endometriosis will be considered as a possible contributory factor to female patients who report haemoptysis

INVESTIGATIONS		
INDICATIONS	INVESTIGATION	OUTCOMES
Quantification of presenting symptoms		
To determine baseline vital signs	Obtain TPR & BP Respiratory rate and SpO ₂	Baseline observations and results of respiratory function tests will be used to determine the patient's response to treatment
To determine lung function	VC and FEV ₁	
<i>Pathology</i> To determine the presence of pathogens in the respiratory tract	Sputum for <ul style="list-style-type: none"> • MC & S • AFBs 12/12 or as indicated • Viral studies as indicated • Spore forming micro-organisms 12/12 or as indicated 	Indications will exist for all investigations ordered Results from all investigations will be used when determining the future management of the patient.
To eliminate septicaemia as a cause of symptoms	Consider obtaining blood cultures if: <ul style="list-style-type: none"> • Temperature > 38° • Patient has a long line or VAD in situ 	
To eliminate airway obstruction or presence of a foreign body as a cause of symptoms	Consider the need for a throat swab if the patient complains of pharyngitis. (Caution with acute epiglottitis)	
<i>Imaging</i> To eliminate the presence of consolidation, collapse, pneumothorax, effusion, space occupying lesions and/or empyema	Chest x-ray	
To eliminate constipation and/or subphrenic abscess as a primary diagnosis	Consider abdominal x-ray if abdominal pain present	

INVESTIGATIONS (cont.)		
INDICATIONS	INVESTIGATION	OUTCOMES
Haematology/Biochemistry To determine the capacity of the blood to carry O ₂ around the body	Full Blood Picture	
To eliminate abnormal renal and/or hepatic function as contributing to the patient's symptoms	U&E's, LFT's, BSL, CRP and IgE	
<i>Other investigations</i> To eliminate acute cardiac events as contributing to chest pain	Consider ECG if pain of cardiac origin is suspected ± Cardiac enzymes	

OPTION 1 - MEDICAL THERAPY AT HOME

Indications

Diagnosis of Respiratory Tract Exacerbation or Lower Respiratory Tract Infection.

Suitability

1. SpO₂ >89% at rest.
2. Patient capable of managing therapy at home and coming back to clinic frequently.
3. Co-morbidity management stable – medical stability
4. Stable home situation

Expected outcomes (Wellness Criteria)

Resolution of symptoms will be reported within two weeks,

1. Less cough and sputum
2. Increase in lung function to near best of last twelve months
3. Weight gain or maintenance
4. Getting back to or ready for normal activities

FOLLOW UP AND DISCHARGE		
ELEMENTS OF CARE	INTERVENTION	OUTCOMES
Diagnosis of uncomplicated Lower Respiratory Tract Infection: <ul style="list-style-type: none"> • SaO₂ >89% • patient willing and capable of managing own treatment at home • no evidence of cardiac or abdominal abnormalities 	Patient to go on Hospital in the Home program Medications prescribed PICC line arranged or Infusaport accessed Referral to pharmacist when appropriate	Patients not meeting criteria will be considered for admission to hospital No patient discharged early home will require admission to hospital within three days of discharge No patient on Respiratory Hospital in the Home program will require admission
<i>Follow up</i>	Arrange follow up appointment for review in 48 hours in clinic	Follow up will be arranged to assess progress of treatment

FOLLOWUP AND DISCHARGE (cont.)		
ELEMENTS OF CARE	INTERVENTION	OUTCOMES
Required investigations prior to review	Specimen jar and request form will be provided for collection of early morning sputum specimen on day of appointment	
<i>Patient education</i>	<p>Provide plan for home care</p> <p>Reinforce need to maintain usual respiratory care regime</p> <p>Teach/review self administration of IV medications</p> <p>Explain/review use of medications & brief side effects profile. Offer CMI from MIMS ® if needed.</p> <p>Ensure patient is aware of indications to return to the hospital</p>	<p>The plan of care will be documented in the patient's medical record</p> <p>The patient will demonstrate an understanding of his or her (self) management and measures which may reduce symptoms.</p>
<i>Certificates and Letters</i>	<p>Provide absence from work/attendance certificates as required</p> <p>Notify patient's GP of attendance</p>	Certificates will be provided as required
<i>Referrals</i>	<ul style="list-style-type: none"> • To respiratory physician • To other health care providers as indicated 	Patients with problems outside the NP's scope of practice will be referred to appropriate health care providers as required
<i>Discharge</i>	Patient meets wellness criteria	<p>Discharge patient home</p> <p>Follow up appointment based on severity of chronic illness.</p>

Option Two –Medical Therapy in Hospital

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DRUG FORMULARY

Aminoglycosides (Tobramycin) and a second antibiotic such as Cefepime®, Timentin® or Tazocin® are the drugs of choice as first line drugs. Other second line agents such as Meropenem, Amikacin and Aztreonam which require microbiological approval may be used if there is no response to the first treatment. The most appropriate drugs need to be chosen regardless of status.

Choice of antibiotic is dependant on a number of factors:

Type of infection, sensitivities, previous response, allergies, drug reactions, renal function, frequency of dosing.

FIRST LINE OF TREATMENT

Tobramycin - Aminoglycoside

Indications - treatment of Gram negative infections

Contraindications - known hypersensitivity

Precautions - renal impairment, vestibular disturbance

Side effects - Ototoxicity, rash, nausea, vomiting, lethargy, renal impairment.

Monitor for nephrotoxicity.

Check trough level + U&E before 3rd dose, then weekly if satisfactory (i.e.<0.5 mg/L).

Check at day 3 after a dose adjustment

Audiology assessment every 4 courses of aminoglycosides.

1st dose to be given under supervision.

Dose	Administration	Script	Comments
If dose not established, start with 10 mg/kg/day in single dose Up to 640mgs daily	Tobramycin (IV) Bag - 50 mL N/S over 30 min or Springfusor®, dilute up to 30mL with N/S, infuse over 30 min		Check previous dose, levels and creatinine level prior to prescribing.

Ticarcillin/clavulanate (Timentin®) - Penicillin

Indications - mixed infections, aerobic and anaerobic, especially if *Ps.aeruginosa*

Contraindications - allergy to penicillin, and cephalosporins or carbapenems, if anaphalaxis.

Precautions - allergy to cephalosporins or carbapenems, renal impairment, low BMI, coagulation disorders

Side effects - hypokalaemia, hyponatraemia, hypersensitivity, rash, myalgia, drug fever

CNS - headache, giddiness

Gastro intestinal, nausea, vomiting and diarrhoea

1st dose to be given under supervision.

Dose	Administration	Script	Comments
6.2g 6 hourly IV	Push dose - 20mL WFI, 5 mins, each 3.1g Bag - 50-100 mL N/S or 5% Dextrose in 30 min		Reduce dose with renal impairment or low BMI

Piperacillin/Tazobactam (Tazocin®) - Penicillin/beta-lactamase inhibitor

Indications - *P. aeruginosa* infections

Contraindications - Allergy to Penicillins, and cephalosprins or imipenems if anaphalaxis

Precautions - renal impairment, bleeding disorders, allergy to cephalosprins or imipenems, or beta-lactamase inhibitor

Side effects - hypokalaemia, hyponatraemia, hypersensitivity, rash, myalgia, drug fever, increased bleeding time

CNS – headache, giddiness

Gastro intestinal - nausea, vomiting and diarrhoea

1st dose to be given under supervision.

Dose	Administration	Script	Comments
4.5g 6 hourly IV	Push - 20 ml WFI. 5 mins Bag - 50-100mL N/S in 20mins		Reduce dose with renal impairment

Cefepime® - Cephalosporin

Indications - *P.aeruginosa* infections

Contraindications - allergy to cephalosporins , penicillin or carbapenems if anaphalaxis.

Precaution - allergy to penicillins or carbopenems

Side effects - usually well tolerated, superinfection

Gastro intestinal - nausea, vomiting and diarrhoea

1st dose to be given under supervision.

Dose	Administration	Script	Comments
2g 12 hourly IV	Push - Each 1g in 20 ml WFI. 5 mins Bag - 50-100mL N/S in 20mins		

SECOND LINE TREATMENT

To be considered if there is no response to the first treatment.

Meropenem - Carbopenem

Indications - community acquired pneumonia, hospital acquired lower respiratory tract infection, *pseudomonas aeruginosa*

Contraindications - demonstrated hypersensitivity, anaphalaxis with penicillin

Side effects - generally well tolerated, nausea and vomiting, diarrhoea, superinfection
1st dose to be given under supervision.

Dose	Administration	Script	Comments
2g tds IV	Push - Each 1g in 20mL WFI, 5 mins Bag 50-100ml N/S, 20 mins		ID approval required Reduce in renal impairment

Aztreonam - monocyclic beta lactam

Indications - treat gram negative organisms, *P.aeruginosa* infections

Contraindications - allergy to aztreonam

Precautions - Penicillin or cephalosporin hypersensitivity

Side effects - rash, vomiting and diarrhoea
increase in liver transaminases

1st dose to be given under supervision.

Dose	Administration	Script	Comments
2g 6 - 8 hrly IV	Push - Each 1g in 20mL WFI, 5 mins		ID approval required Usually reserved for B-lactam hypersensitivity Reduce dose in moderate to severe impairment.

INHALED TREATMENTS

Tobramycin (inhaled) Pari LC plus nebuliser

Indications - Ps Aeruginosa infection

Contraindications - known hypersensitivity

Side effects - broncho constriction,

1st dose to be given under supervision

Dose	Administration	Script	Comments
160mg inhaled twice daily.	2 x 80mg/2.0mL ampoules (4.0ml in nebuliser.)	OP use Rx	Preservative free formulation has Disodium edetate as only inactive agent.

Colistin (inhaled) (Tadim®) Pari LC plus nebuliser

Indications - Ps Aeruginosa infection

Contraindications - known hypersensitivity

Side effects - broncho constriction,

1st dose under supervision

Dose	Administration	Script	Comments
2 million units BD	Disolve one vial with 2ml N/S & 2nd vial with 2ml WFI - 4.0mL in nebuliser.	OP use Rx	Use preservative-free solution

ORAL TREATMENTS

Ciprofloxacin - Quinolone

Indications - *Ps Aeruginosa* infection

Contraindications - known hypersensitivity, not for under 16 yrs

Side effects - Photosensitivity, rash, tendonitis, confusion, GI upset.

Dose	Administration	Script	Comments
500mg - 750mg bd	Oral	OP use Rx	PBS Authority - known PsA Avoid giving within 2 hrs of iron, calcium, magnesium.

Cotrimoxazole (Septrin Forte® or Bacrim DS®) - Sulphonamide

Indications - treatment and prophylaxis of common infections

Contraindications - known hypersensitivity to sulphur drugs or trimethoprim, severe hepatic or renal impairment, late pregnancy

Side effects- Photosensitivity, fever, rash, vomiting diarrhoea, hyperkaemia, blood dyscrasias, hypersensitivity reaction.

Dose	Administration	Script	Comments
160/800mg bd	Oral	OP use Rx	PBS Authority prescription for increased quantities (standard PBS = 10 tablets)

Dicloxacillin - Penicillin

Indications - staphylococcal chest infection

Contraindications - known hypersensitivity, allergy to penicillins, cephalosporins or carbopenems if anaphalaxis

Precautions - allergy to cephalosporins or carbopenems

Side effects - Dyspepsia, abnormal LFT's,

Dose	Administration	Script	Comments
1.0 gm 4 times daily	Oral	OP use Rx	PBS Authority prescription for increased quantities (standard PBS = 24 capsules) Best absorbed on empty stomach.

Review Date and Plan

This protocol will be reviewed once per year - The best time being the month of January. New research findings will be assessed and incorporated into the protocol on discussion with the rest of the Cystic Fibrosis Team.

Discussion will be listed on the Multidisciplinary Team Meeting Agenda at the end of the month after a literature review that has been commenced at the beginning of the month of January.

Implementation Plan

The Cystic Fibrosis Clinic is set up and functioning. The Nurse Practitioner currently assesses patients prior to seeing the Medical Practitioner.

When the protocol has been signed off, patients requiring Home intravenous antibiotics will be managed by the Nurse Practitioner whilst they remain within the bounds of the protocol.

The Medical Practitioner will be kept informed of the patient's progress.

Evaluation Plan.

Any issues raised regarding the Protocol will be listed for discussion at the Multidisciplinary team Meeting.

An annual review of the protocol will be carried out by the Nurse Practitioner and peers, being members of the Multidisciplinary Team, at the end of January or beginning of February.