ntroduction

Scope

This procedure applies to all adult patients with CF who are prescribed inhaled antibiotics, antifungals and mucolytics.

All adult patients should receive a DRA if they have not taken the medicine before, or some time has elapsed since they last took it (e.g. over 1 year approx.). This ensures patient can tolerate the treatment at home and they will be less likely to have a significant reaction.

The DRA procedure should take place in a hospital setting during working hours with access to emergency facilities.

Any new treatment should be assessed after a few months as some patients experience milder adverse effects that may not be apparent during the DRA procedure.

It is important that practitioners who administer the test dose are competent in the administration and assessment of response to the inhaled medication.

It is also important that each dose is prescribed correctly, and that documentation of the outcome is clear and stored in the patients record.

The prescriber is responsible for the correct prescription of the inhaled medicine and any pre- or post-bronchodilator required.

Patients with FEV1 < 1 litre or low % predicted

These patients may not be suitable for every option especially if very irritant. Special care should be taken when carrying out the DRA in these patients.

Confirm the result with medical staff as the % change may not be as accurate and the absolute change in millilitres should also be considered.

As the numbers may be misleading the patient's overall response including respiratory symptoms should be considered when deciding on the outcome.

Technique and equipment

Patients should be taught correct technique of how to reconstitute and / or prepare the medicine for inhalation/ nebulisation. Correct breathing technique should also be assessed and taught if required. This can be done by the nurse or physiotherapist carrying out the assessment. The pharmacist can assist with patient education where required.

Relevant equipment including cleaning instructions and advice about ongoing maintenance and replacements should be given after completion of the trial.

	Preparation	When	Responsibility
1	Decision to commence nebulised treatment at clinic, annual review, ward review, in-patient or MDT discussion	Decision to treat	Clinician / MDT
2	Book patient appointment as a ward attender	Preparation	CF nurse specialist (CFNS)
3	Inform pharmacist of booked date (at least 1 week notice) More urgent tests by special arrangement.	Preparation	CFNS
4	Out-patient prescription completed and sent to pharmacy (mark prescription with appointment date)	Preparation	Pharmacist/ clinician
5	Pharmacy orders 1 month pack for named patient (stock is not held in pharmacy)	Preparation	Pharmacist/ technician
6	Stock held in pharmacy dispensary until day of test labelled with patient's name	Preparation	Pharmacist/ pharmacy
7	Prescribe test dose on the Once only section of the Prescription and Administration Chart including pre-dose bronchodilator if needed. In addition, prescribe emergency dose of bronchodilator for all patients - to be given in event of bronchoconstriction.	Preparation	Pharmacist / clinician
8	Obtain supply from pharmacy. Store appropriately on ward until date of test (some items are refrigerated).	Preparation	CFNS / porter / pharmacy

	DRA procedure	When	Responsibility
1	Collect all equipment required (nebuliser, inhaler, spirometer etc.). Remove 1 dose for test dose and store the remaining pack appropriately until test completed e.g. put back in fridge.		CFNS/ physio
2	Explain procedure to patient including nebuliser or inhaler technique breathing technique. Provide patient information leaflets as available.	Test procedure	CFNS/ physio
3	Check airway clearance is optimised to avoid any issues with sputum retention prior to test		
4	Confirm patient had no contra-indications to the procedure such as haemoptysis, current exacerbation, recent sinus surgery etc.	Test procedure	CFNS/ physio
5	Inform the patient to report any adverse effects immediately.	Test procedure	CFNS/ physio
6	Refer to NHS Lothian Guideline for Inhaled and Nebulised Medicines. Found here xxxxx		
7	If pre-test bronchodilator required e.g. salbutamol 200mcg, give this 5-10 minutes before baseline spirometry. Patients who usually do not take a bronchodilator can be booked without pre-dose.	Test procedure	CFNS/ physio
8	Baseline observations measured (spirometry, oxygen saturations and auscultation)	Test procedure	CFNS/ physio
9	Test dose given using appropriate nebuliser/ chamber or inhaler device (see nebuliser guide for details)	Test procedure	CFNS/ physio
10	Patient monitored for any immediate adverse effects	Test procedure	CFNS/ physio

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	Monitoring and Result	When	Responsibility
1	Repeat spirometry and oxygen saturations after 10 minutes	After test	CFNS/ physio
2	Calculate the % change in FEV1 from baseline (see below) and document result	After test	CFNS/ physio
3	Confirm if pass/ fail test - <10% change = pass - 10-15% and NO symptoms = pass - 10-15% with symptoms (cough, wheeze) = fail - >15% = fail	After test	CFNS/ physio
4	Pass - give the patient 1 month supply, using an out-patient prescription - inform GP to continue prescription as per Shared Care Guidelines For long-term treatment - update database with new medicine - send GP a pharmacy letter via CF database or inform CF pharmacist - review treatment at routine clinic appointment Patient Education - Ensure patient knows how new treatment fits in along with existing inhaled treatments e.g. bronchodilators, mucolytics, airway clearance, then inhaled antibiotics and steroids last	After test	CFNS/ pharmacist/ physio
5	Fail For patients who fail the test monitor closely and administer bronchodilator. Repeat the FEV1 after a further 10 minutes. Keep monitoring until FEV1 reduction returns to 10% or less from baseline.	After test	CFNS / physiotherapist
6	If patient's FEV1 remains > 10% from baseline or they have ongoing symptoms, then seek a medical review	After test	CFNS /clinician
7	Repeat testing after failed test - rebook patient for a repeat assessment with a pre-test bronchodilator prescribed	After test	CFNS / physiotherapist
8	The results of the test including observation results and any treatments given should be clearly documented in the patient's electronic record. Use code '\DrugRes' and add [Space] within Clinical Note in Trak to bring up standard text.	After test	CFNS/ physiotherapist

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Date	Version updated	Amendment	Written by	Approved by
			DM	

References

Association of Charter Physiotherapists in Cystic Fibrosis, Standard operating procedure – drug response assessment

Summary of product characteristics for each medicine found at: $\underline{www.emc.org.uk}$

Safe Use of Medicines Policy and Procedures, Area Drug and Therapeutics Committee, NHS Lothian. Available at: https://policyonline.nhslothian.scot/Pages/default.aspx

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