Taddle Creek

Family Health Team

MEDICAL DIRECTIVE

Title:	Spirometry Testing	**Number:**	TCFHT-MD11
Activation Date:	10-06-2014	**Review Date:**	July 27, 2023
Next Review	July 27, 2024		

Sponsoring/Contact Person(s) *(name, position, contact particulars):*

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Order and/or Delegated Procedure:

Appendix Attached: _X_ No __ Yes
Title:

For patients referred by a physician or nurse practitioner for spirometry/bronchodilator responsiveness testing, the authorized implementer may perform the following:

- Perform spirometry testing (pre- and post-bronchodilator)
- If reversibility testing is required, administer a specified dose of bronchodilator (salbutamol or ipratropium) via inhalation with disposable spacer device (dose as per American Thoracic Society/European Respiratory Society [ATS/ERS] Standards for Spirometry[1])

Recipient Patients:

Appendix Attached: __ No _X_ Yes
Title: Appendix A – Authorizer Approval Form

Recipient patients must:

- Be active patients of a TCFHT primary care provider who has approved this directive by signing the Authorizer Approval Form
- Age of 6 and over
- Have a suspected or confirmed diagnosis of asthma or COPD
- Meet the conditions identified in this directive

Authorized Implementers:

Appendix Attached: __ No _X_ Yes
Title: Appendix B – Implementer Approval Form

Implementers must:

- Be TCFHT employed Regulated Health Care Providers or Physician Assistant (under the supervision of a physician).

- Have basic life-support training[2]
- Successfully complete a recognized spirometry training course. Preferred training is SpiroTrec (which includes 16 hours of pre-workshop learning, an 8 hour workshop and subsequent quality assurance review of 5-10 tests/month for 3 months) offered by the Ontario Lung Association[2]. Accessible from: http://www.resptrec.org
- Sign the Implementer Approval form

Indications:

Appendix Attached: __ No _X_ Yes
Title: Appendix C - Reasons for relative contraindications

The authorized implementers may apply this directive pursuant to a physician or nurse practitioner's order.

Absolute Contraindications:

- Patient/POA refusal

Relative Contraindications to Spirometry[5]:

- Cerebral aneurysm
- Recent brain surgery (within 4 weeks)
- Recent concussion with ongoing symptoms
- Significant glaucoma
- Recent eye surgery (within 4 weeks)
- Recent sinus surgery or middle ear surgery or infection (within 4 weeks)
- Acute disorders affecting performance (nausea, vomiting, dizziness)
- Pneumothorax (currently present)
- Uncontrolled pulmonary hypertension
- Hemoptysis, active TB, or hepatitis B (infection control procedures must be taken)
- Recent abdominal or thoracic surgery (within 4 weeks)
- Recent MI (in past 4 weeks) unstable angina or pulmonary embolism, acute cor pulmonale
- Non-compensated heart failure
- Significant atrial/ventricular arrhythmias
- Systemic hypotension or severe hypertension (>200/120mmHg)
- Significant aortic aneurysms
- Late term pregnancy or pregnancy with an incompetent cervix
- History of syncope related to forced exhalation/cough
- Physical conditions predisposing to transmission of infections, such as hemoptysis, significant secretions, or oral lesions or oral bleeding
- The following conditions may result in suboptimal or inaccurate lung function results: age <6yrs, chest or abdominal pain of any cause, oral or facial pain exacerbated by a mouthpiece, stress incontinence, dementia, or confused state.

- Recent diagnosis with covid in the past 10 days or persistent respiratory symptoms due to recent covid that could impact the quality of the spirometry test

**ATS guidelines have shorter wait times before spirometry can be done, however as a community facility we choose safer options. However, the referring MD can review in case-by-case basis (i.e. time post MI for spirometry is at least 4 weeks, but ATS guidelines say contraindicated if acute MI within 1 week)

Contraindications to salbutamol: hypersensitivity to salbutamol
Contraindications to ipratropium: hypersensitivity to ipratropium, atropine, bromide, soya lecithin or peanuts

Consent:

Appendix Attached: X No ___ Yes
Title:

Consent is implied upon referral from physician/NP for spirometry testing. The authorized implementer will call the patient prior to appointment to introduce the test, explain which medications/activities to withhold prior to procedure and will further obtain verbal consent from the patient or POA.

Guidelines for Implementing the Order/Procedure:

Appendix Attached: ___ No X Yes
Title: Appendix E – Procedure for Spirometry Testing

The implementer shall be able to perform spirometry and reversibility testing, through the administration of a short-acting bronchodilator, as well as advising patients on which inhaled medication to withhold prior to spirometry testing.

- The decision to avoid bronchodilators before testing depends on the reason for the test. If post-bronchodilator testing is to be performed to diagnose an underlying lung condition, the patient may/should withhold the following medications prior to spirometry testing (note: the patient must be told they may use their rescue inhaler for symptoms if needed)[3,5].

Medication	**Withholding Time Prior to Spirometry**
Short-acting beta2 agonists (SABA) e.g. salbutamol, terbutaline	4-6 hours
Short-acting anticholinergic (SAAC) e.g. ipratropium	12 hours
Long-acting Beta2 agonist (LABA) e.g. salmeterol, formoterol, budesonide and formoterol (Symbicort) indacaterol, vilanterol, olodanterol	24 hours 36 hours
Long-acting anticholinergic/muscarinic antagonist (LAAC/LAMA) e.g. Glycopyrronium, tiotropium, aclidinium, umeclidinium	36-48 hours
Corticosteroids (ICS and oral) e.g. fluticasone, budesonide, ciclesonide, beclomethasone, mometasone, prednisone	Do not withhold*
Leukotriene receptor antagonists e.g. Montelukast (Singulair), Zafirlukast (Accolate)	24 hours
Phosphodiesterase enzyme inhibitor e.g. Theophylline (Theo-Dur)	24-48 hours
Antihistamines	Do not withhold

- If the test is to determine the response to a medication, then the medications should not be withheld (with the exception of SABA's and SAAC's, as these will be delivered as part of the test to assess for reversibility) [3].

Pt should avoid the following activities before spirometry/ bronchodilator responsiveness testing**:

- Eating a large meal within 2 hours of test
- Smoking and/or vaping and/or water pipe use within 1 h before testing (to avoid acute bronchoconstriction due to smoke inhalation)
- Consuming intoxicants within 8 h before testing (to avoid problems in coordination, comprehension, and physical ability)
- Performing vigorous exercise within 1 h before testing (to avoid potential exercise-induced bronchoconstriction)
- Wearing clothing that substantially restricts full chest and abdominal expansion (to avoid external restrictions on lung function)

** These pre-spirometry questions should be asked at the time of appointment booking AND again upon arrival on the day of their spirometry test. Any deviations from their initial responses must be recorded in the custom form used for their spirometry documentation.

Until GLI-Global data available for Easy-On PC spirometry program, GLI-Other data set to be used.

Method for performing reversibility spirometry testing[1]:

Note: a current height and weight need to be recorded for each spirometry visit (to the nearest decimel for height only with our system)*

CRE performing spirometry must follow IPAC (See appendix F)

1) The patient performs three acceptable and two repeatable maneuvers, as per ATS/ERS Standards for spirometry (not to exceed 8 attempts)[1]

2) One of the following bronchodilators is administered via MDI inhalation using a disposable spacer device[4]:

Medication	ATS/ERS Dose Recommendation	Wait Time
Salbutamol	4 inhalations** of 100 mcg (Children <12yoa: 2 inhalations*)	15 min
Terbutaline	2 inhalations** of 500 mcg	15 min
Ipratropium	8 inhalations** of 20 mcg	30 min

*In persons aged 25 years or older, for whom a reliable height measurement has been made previously in the same facility, remeasuring height at subsequent visits within 1 year may not be necessary.[5]

**A smaller dose may be used if the patient is at risk of or has had an uncomfortable reaction to these medications (e.g., shakiness, trembling, or heart palpitations)
Note: beta blockers interfere with efficacy of salbutamol. If a patient is on a beta blocker and is referred for spirometry, please notify PCP to reassess need for beta blocker prior to spirometry testing.

3) After appropriate wait time, the post-bronchodilator test begins. A minimum of three acceptable and two repeatable maneuvers must be obtained before analysis of findings.

Documentation and Communication:

Appendix Attached: _X_ No __ Yes
Title:

The implementer will document spirometry results directly into the progress notes of the patient's EMR using appropriate Respiratory Program Custom Form. The primary care provider will be alerted, so that appropriate follow up can be conducted. A PDF copy of the spirometry report should also be entered into the progress notes as an attachment to the Respiratory Program Custom Form note. Implementers should use Respiratory Program Custom Forms: "Diagnosis Confirmation", "Asthma Control" or "COPD Control".

The final report must include (at minimum) [3]:

- Date and time of the test
- Patient details: age, gender, height and weight
- Flow-volume graph and volume-time graph
- Implementer's name
- Implementer's comments on the quality of the test, which may aid interpretation.

Review and Quality Monitoring Guidelines:

Appendix Attached: _X_ No __ Yes
Title:

- Routine renewal will occur annually on the anniversary of the activation date. Renewal will involve a collaboration between the authorizing primary care providers and the authorized implementers.
- At any such time that issues related to the use of this directive are identified, TCFHT must act upon the concerns and immediately undertake a review of the directive by the authorizing primary care providers and the authorized implementers.
- This medical directive can be placed on hold if routine review processes are not completed, or if indicated for an ad hoc review. During the hold, implementers cannot perform the procedures under authority of the directive and must obtain direct, patient-specific orders for the procedure until it is renewed.
- This medical directive should be reviewed with each update of the ATS/ERS or CTS Standards for Spirometry.
- Quality control checks are to be regularly performed[4].
    1. Spirometer must, at minimum, be calibrated on the days that the spirometer will be in use. This is done using a 3L syringe, injected into the spirometer at differing speeds in order to verify the volume calibration of spirometers. This will be recorded on the program and documented on the maintenance log. Calibration standards as of 2019 reduced to +/- 2.5%.
    2. Monthly biological control testing by the CRE performing the spirometry can be done in addition to the 3L syringe but isn't required. It can be done as a quick rough check if you suspect a problem.

Note: Any deviation in the accuracy checks should be followed up with a calibration of the spirometer, and then performed again. Further deviation indicates there is a fault in the equipment, and should be followed up with the manufacturer.

References:

1. Miller MR, et al. Series "ATS/ERS Task Force: Standardisation of Lung Function Testing" – Standardisation of spirometry (Number 2 in the Series). *Eur Respir J*, 2005; 25: 319-338.
2. Coates AL, et al. Spirometry in primary care. *Can Respir J*, 2013; 20(1): 13-21.
3. The Lung Association (2013). The Spirometry Training and Educator Course
4. The Lung Association of Ontario (2013, Dec). Primary Care Asthma Program: Spirometry Manual.
5. Graham B, et al. Standardization of Spirometry 2019 Update. American Journal of Respiratory and Critical Care Medicine Volume 200 Number 8 | October 15 2019

Appendix A:

Authorizer Approval Form

Name	Signature	Date

Appendix B:

Implementer Approval Form

To be signed when the implementer has completed the required preparation, and feel they have the knowledge, skill, and judgement to competently carry out the actions outlined in this directive.

Name	Signature	Date

Appendix C:

Reasons for Relative Contraindications[4]

Relative Contraindications	Comments
• Cerebral aneurysm • Recent brain surgery • Recent concussion • Recent eye surgery • Significant glaucoma	Spirometry may lead to increased intraocular pressure in most patients and a 3-4 week recovery post-surgery is recommended before testing
• Recent sinus surgery or middle ear surgery or infection	There is a risk that forced maneuvers can cause pain and even ear drum ruptures in cases of middle ear infection
• Pneumothorax • Significant aortic aneurysm* • Recent thoracic surgery** • Recent abdominal surgery • Pregnancy***	*Spirometry causes increases in intrathoracic and intra-abdominal pressure that may increase blood pressure **Physiotherapy and coughing has been shown to be beneficial after cardiothoracic and abdominal surgery. Cough increases intrathoracic pressure up to 400cmH2O compared with 70cmH2O- 200cmH2O during spirometry. The risk is therefore low in most patients. ***Lung function tests may increase the risk of early delivery in the case of an incompetent cervix
• Systemic hypotension or severe hypertension (e.g., >200/120mmHg) • Significant atrial/ventricular arrhythmia • Non-compensated heart failure • Recent myocardial infarction (MI) or pulmonary embolus • History of syncope related to forced exhalation/cough	Exercise testing one week after MI appears to be safe, however, caution is necessary where persistent myocardial ischemia exists. The use of beta2- agonists when doing post-bronchodilator spirometry can also be a risk for people with these conditions, although the risk of a single administration is likely to be minimal.
• Active tuberculosis • Hepatitis B • Hemoptysis or oral bleeding	Infection control procedures must be taken according to local procedures
• Inability to follow direction (e.g., confusion, dementia, young age, language barrier)	In some cases, successful spirometry can be done with increased coaching and aid of an interpreter

Note: Recent Indicates within 6 weeks.

Appendix D:

Considerations for Spirometry in young children (<12yrs)[4]

☐ Children have higher elastic recoil of the lungs than adults and therefore, have faster emptying of the lungs (some children are able to exhale completely in 1 sec).

☐ Minimum expiratory time is 3 sec for children ≤ 10 years of age rather than 6 sec for adults. However, the requirement of a plateau < 25mL in the final 1 sec of exhalation remains (ATS/ERS standards 2005)

☐ If the child can exhale their lung volume in < 2 sec, the technologist must override the automatic rejection of the test.

☐ Criteria include:

- For tests with FVC > 1.0 L
  - The 2 largest FVC values are within 150mL of each other
  - The 2 largest FEV1 values are within 150mL of each other
- For tests with FVC < 1.0 L
  - The 2 largest FVC values must be within 100mL of each other
  - The 2 largest FEV1 values must be within 100mL of each other

☐ The back-extrapolated volume used for the beginning of the test must be ≤ 100mL or 5% of FVC, whichever is greater.

☐ When a child performs spirometry testing, they must rapidly inspire to maximal lung volume and prevent breath holding prior to forced exhalation (ATS/ERS 2005)

☐ Ensure an appropriately sized mouthpiece for a better seal

☐ Ensure the use of nose clips (CRE to make note if unable to use or unable to keep on nose)

Appendix E:

Procedure for Spirometry Testing

Preparation

You will need:

- Spirette
- Nose clips
- Bronchodilator
- filters and adaptors
- Disposable spacer for bronchodilator administration
- Demo spirette
- Solid chair
- 3 litre syringe

1. Open Easy-On program from PC desktop
2. Calibrate spirometer before test > utilities > check calibration > 3 Litre syringe calibration
3. Monthly biological quality control test can be done, but not required
4. CRE performing spirometry must follow IPAC (see appendix F)
5. Open patient EMR, prepare the custom form based on the reason for referral "Resp.Prog. -Dx Confirmation (Asthma & COPD) (2022)" or "Resp.Prog.-Control Assessment (Asthma) (2019), or " Resp.Prog.-Control Assessment (COPD) (Nov 2016)"
6. Find or enter the patient on Easy-On:
    a. For a new patient: Click "new". Enter all available information from patient's chart (ex. Patient ID [EMR number], DOB, name, etc.)
    b. For a follow-up patient: find patient on list under "patients"

History / Demonstration

1. Explain the purpose of the test to the patient
2. Measure patient's height and weight, enter into Easy-On PC profile and EMR
3. Obtain history of patient's lung health using appropriate Respiratory Program Custom Form in EMR, fill in remainder of profile on Easy-On
4. Explain one manoeuvre of spirometry test, then demonstrate with demo spirette. Ensure patient understanding

Pre-Bronchodilator Test

5. Press "test" >FVL (ex/in)
6. Enter ambient temperature and humidity values as prompted (altitude is already set and fixed). Recalculate BTPS and Confirm.
7. Block spirette as prompted
8. Perform test! Ensure you obtain 3 acceptable with at least 2 repeatable maneouvres

Post-Bronchodilator Test

1. Administer appropriate bronchodilator, as per medical directive, via disposable spacer
2. Wait appropriate amount of time, based on medication used
3. Click on "Add Post" and perform test!
4. Click on "comments" on the results page to enter interpretation notes.
5. When testing is complete, click on "Print Menu". Select "PDF file"
6. Name the file "last name, first name" and save to desktop
7. Now drag PDF from desktop into your Custom Form note on your patient's EMR
8. Once entered into the patient's chart, delete the file from the desktop

Appendix F:

Infection Prevention & Control and Minimization of Risk of Transmissible Diseases

- Full PPE recommended: Gown, N95 fitted mask, Face Shield, Gloves
- HEPA Filter: Tornado AC550 – 5.1-6.4 air exchanges per hour meets
  - CTS recommendations are minimum 6 air exchanges per hour (AER)
  - Spacing patient appointments by 1 hr will meet this requirement
- COVID-19 community case numbers – when peaking, pause spirometry until positive cases trending down again
- Disinfect: CAVI wipe computer, spirometer, Salbutamol/Ipratropium inhalers, desktop
- Discard: single use spirettes, filters, nose clips, disposable cardboard spacers
- In S306 Education Room (283 sqft) and has the necessary HVAC air clearance of 6 per hour
- Spirometer and patient to be separated from CRE by minimum 2m (6 ft) distance
- Patient to face forward and away from clinician
- Do NOT recommend plexiglass barriers as expected to impair air flow and proper ventilation
  - Reference:
    - https://www.ontariofamilyphysicians.ca/tools-resources/covid-19-resources/clinical-care-office-readiness/ipac-summary.pdf

NOTES:

- Wt/Ht Measures:
  - The height must be measured without shoes, with the feet together, standing as tall as possible with the eyes level and looking straight ahead, and the back flush against a wall or stadiometer.
  - for whom a reliable height measurement has been made previously in the same facility, remeasuring height at subsequent visits within 1 year may not be necessary.
- Spirometer
  - Daily calibration verification at low, medium, and high flow: If the calibration verification fails, check for and remediate problems and repeat calibration verification
  - If an in-line filter is used in spirometry testing then it must also be used during recalibrations and verifications
- Within Maneuver Evaluation
  - The back-extrapolated volume (BEV) is the volume of gas that has been expired from maximal lung volume to Time 0 and is included in the FEV_1 and FVC measurements (see Figure 1 of the full standards article). To achieve an accurate Time 0 and ensure that the FEV_1 comes from a maximal effort, the BEV must be <5% of the FVC or 0.100 L, whichever is greater. The 0.100-L tolerance is a reduction from the 0.150-L tolerance in the 2005 standards (5).