Name of Policy:	**Methacholine Challenge Test**
Policy Number:	3364-136-PF-06
Department:	Respiratory Care
Approving Officer:	Associate VP Patient Care Services / Chief Nursing Officer
Responsible Agent:	Director, Respiratory Care
Scope:	The University of Toledo Medical Center Respiratory Care Department

THE UNIVERSITY OF TOLEDO MEDICAL CENTER

Effective Date: June 1, 2020
Initial Effective Date: July 1, 1978

_____ New policy proposal
_____ Major revision of existing policy
__X__ Minor/technical revision of existing policy
_____ Reaffirmation of existing policy

(A) Policy Statement

The approved procedure for challenge tests will be followed by all Pulmonary Function staff members. The procedure is based on The American Thoracic Society Guidelines.

(B) Purpose of Policy

1. To standardize the testing procedure, thereby providing the greatest possible accuracy and reproducibility of test results.
2. Methacholine is used to assist in making a positive diagnosis of asthma as well as documenting severity and following changes.
3. To confirm a diagnosis of bronchial hyper-reactivity in subjects who do not have clinically apparent asthma (FEV1 of at least 70% predicted value) yet do have chronic cough, recurrent respiratory infection and history of wheezing with objective clinical documentation.

(C) Procedure

Patient Preparation

1. Power, warm up and calibrate Pulmonary Function Testing system.

2. Gather material needed: Special methacholine administration kit; properly labeled dosages of methacholine from Pharmacy. Source of pressurized oxygen. Albuterol unit dose with an updraft nebulizer or Albuterol MDI (4 puffs) as appropriate. Review and confirm physician's order. Order should be Pulmonary Function Test I. Maintain appropriate infection control maneuvers.

3. Pharmacy will mix the solution in the following concentrations: 0.025 mg/ml, 0.25 mg/ml, 2.5 mg/ml, 10.0 mg/ml, and 25 mg/ml. They will be labeled according to Pharmacy policy.

4. Reconcile current patient medications. If they include any of the medications listed in Appendix I and have not been held for the recommended interval, inform the patient's physician. Explain that such drugs may interfere with the challenge and possibly reschedule test. Smoking and drinking cola or chocolate beverages should be refrained from at least 6 hours prior to testing. Exercise and exposure to cold air should be avoided for at least 2 hours before test.

5. Educate patient regarding testing procedure.

Testing Procedure

Perform methacholine challenge testing according to Appendix II

Contraindications

1. Baseline pulmonary function tests with FEV1 less than 1-1.5 liters or less than 70% of the predicted values.
2. Patients with known hypersensitivity to methacholine or other parasympathimetic agents.
3. Repeated administration of Provocholine other than on the day that a patient undergoes challenge of increasing doses.
4. Patients receiving beta-adrenergic blocking agent which can cause a prolonged and exaggerated response to methacholine Cl as well as interfering with accepted modalities of treatment.
5. Pregnancy or nursing mothers.
6. Children below 5 years of age.

Precautions

1. Females of childbearing age: challenge should be performed either within ten days following the onset of menses or within two weeks of a negative pregnancy test.
2. Active infectious disease.
3. Cardiovascular disease with bradycardia.
4. Vagotonia
5. Peptic ulcer disease
6. Epilepsy
7. Thyroid disease
8. Urinary tract obstruction
9. Symptomatic coronary artery disease
10. History of MI
11. CHF
12. Renal/liver failure
13. Documented psychiatric disease
14. Inability to understand the procedure (in the opinion of the MD requesting the test)
15. Serious illness
16. Systolic B/P >170 or <100
17. Diastolic B/P >110 or <60

Possible Side Effects

1. Chest tightness
2. Mild cough
3. Mild wheezing
4. Dizziness, lightheadedness and chest pain associated with spirometry maneuver

Reference:

"Guidelines for Methacholine and Exercise Challenge Testing- 1999" Official statement of the American Thoracic Society- July 1999, Amer J Respir Crit Care Med Vol 161. pp 309 – 329, 2000 www.atsjournals.org

Approved by:		**Review/Revision Date:**	
		01/01/1981	08/05/2008
		06/24/1984	06/30/2011
/s/	6/15/2020	07/08/1987	02/28/2014
Michael Taylor	Date	06/06/1990	05/01/2017
Director, Respiratory Care		06/06/1993	06/01/2020
		09/05/1996	
		07/27/1999	
/s/	6/19/2020	05/30/2002	
Monecca Smith	Date	08/11/2005	
Associate VP Patient Care Services / Chief Nursing Officer			
Review/Revision Completed By: *Director, Respiratory Care*		**Next Review Date:** June 2023	
Policies Superseded by This Policy:			

It is the responsibility of the reader to verify with the responsible agent that this is the most current version of the policy.

Name of Policy:	**Appendix I to Methacholine Challenge Test**
Policy Number:	3364-136-PF-06
Department:	Respiratory Care
Approving Officer:	Associate VP Patient Care Services / Chief Nursing Officer
Responsible Agent:	Director, Respiratory Care
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THIS OFFICIAL STATEMENT OF THE AMERICAN THORACIC SOCIETY WAS APPROVED BY THE ATS BOARD OF DIRECTORS, JULY 1999

FACTORS THAT DECREASE BRONCHIAL RESPONSIVENESS

Medications	**Minimum Time Interval from Last Dose to Study**
Short-acting inhaled bronchodilators Such as isoproterenol, isoetharine, Metaproterenol, albuterol, terbutaline	8h
Medium-acting bronchodilators Such as ipratropium	24h
Long-acting bronchodilators Such as salmeterol, formoterol, tiotropium	48h (perhaps 1wk for tiotropium)
Oral bronchodilators	
Liquid theophylline	12h
Intermediate-acting theophylline	24h
Long-acting theophylline	48h
Standard Beta $_2$ agonist tablets	12h
Long-acting Beta $_2$ agonist tablets	24h
Cromolyn sodium	8h
Nedocromil (Tilade)	48h
Hydroxazine, Cetirizine	3d
Leukotriene modifiers	24h

Foods
Coffee, tea, cola drinks, chocolate Day of Study

Note: the authors *do not* recommend routinely withholding oral or inhaled corticosteroids, but their anti-inflammatory effect may decrease bronchial responsiveness. Inhaled corticosteroids may need to be withheld depending on the question being asked.

Reference: Am J Respir Crit Care Med Vol 161. pp 309-329, 2000

Approved by:		**Review/Revision Date:**
		01/01/1981 08/05/2008 06/24/1984 06/30/2011 07/08/1987 02/28/2014 06/06/1990 05/01/2017 06/06/1993 06/01/2020 09/05/1996 07/27/1999 05/30/2002 08/11/2005
/s/ Michael Taylor Director, Respiratory Care	6/15/2020 Date	
/s/ Monecca Smith Associate VP Patient Care Services / Chief Nursing Officer	6/19/2020 Date	
Review/Revision Completed By: *Director, Respiratory Care*		**Next Review Date:** June 2023
Policies Superseded by This Policy:		

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Name of Policy:	**Appendix II to Methacholine Challenge Test**
Policy Number:	3364-136-PF-06
Department:	Respiratory Care
Approving Officer:	Associate VP Patient Care Services / Chief Nursing Officer
Responsible Agent:	Director, Respiratory Care
Scope:	The University of Toledo Medical Center Respiratory Care Department

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Procedure to perform Challenge test

1. Parameters to be measured:
    a. Flows and volumes from a forced expiratory maneuver and/or
    b. Specific airway conductance (GAW/VL)

2. Nebulization method: Special methacholine nebulizer set-up. Run the 5ml solution at 6L for 2 minutes.

3. Threshold Response Criteria:

    a. For normals: change in GAW/VL > 40% from control
    b. For asthmatics: change in FEV1 > 20% from control
    Change in GAW/VL > 40% from control

4. Drug Concentrations for methacholine challenge:
    0.025 mg/ml, 0.25 mg/ml, 2.5 mg/ml, 10 mg/ml, 25 mg/ml

5. Performance Steps
    a. Measure baseline parameters.
    b. Nebulize diluent (sodium chloride) in which methacholine is dissolved. Patient is asked to wear a nose clip and breathe normally through the mouthpiece of a nebulizer.
    c. Perform measurements at 30, 90 and 180 seconds after inhalation.
    d. If the FEV1 falls by greater than 20% from the baseline measurement, terminate procedure since the subsequent response to the pharmacologic agent is uninterpretable. Following insignificant response to control continue with following steps.
    e. A new nebulizer will be used for each subsequent medication administration to assure accuracy of concentrations.
    f. Nebulize lowest concentration of drug for 2 minutes.
    g. Repeat measurements as in step d.
    h. Administer the 2 minute inhalations in ascending order of the serial concentrations, repeating steps d, f and g until threshold response is achieved.
    i. Periodic auscultation, pulse rate and /or blood pressure may be monitored to assist in patient assessment and test interpretation.

j. After completion of Methacholine challenge delivery, bronchoconstriction is then reversed:
    1. Administer Albuterol unit dose (2.5 mg Albuterol / 0.5 mL)
    2. Repeat measurements.
    3. In the event of a positive response, measure parameters until return to near baseline values.

Data Presentation

1. The results are reported as a percent decrease in FEV1 from baseline (or post diluent if diluent step is used).
2. Data should be presented for each step of protocol, including the post bronchodilator test.
3. The highest FEV1 value from acceptable tests is selected for outcome variable.
4. The PC20 is calculated from change in FEV1.

Variability of Test

1. Test should be performed between 9am and 5pm.
2. Patients with excessive variability in measured baseline values (greater than 5% of the FEV1) should not be tested.

Approved by:		**Review/Revision Date:**
/s/	6/15/2020	01/01/1981 08/05/2008 06/24/1984 06/30/2011 07/08/1987 02/28/2014 06/06/1990 05/01/2017 06/06/1993 06/01/2020 09/05/1996 07/27/1999 05/30/2002 08/11/2005
Michael Taylor Director, Respiratory Care	Date	
/s/	6/19/2020	
Monecca Smith Associate VP Patient Care Services / Chief Nursing Officer	Date	
Review/Revision Completed By: *Director, Respiratory Care*		**Next Review Date:** June 2023
Policies Superseded by This Policy:		

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