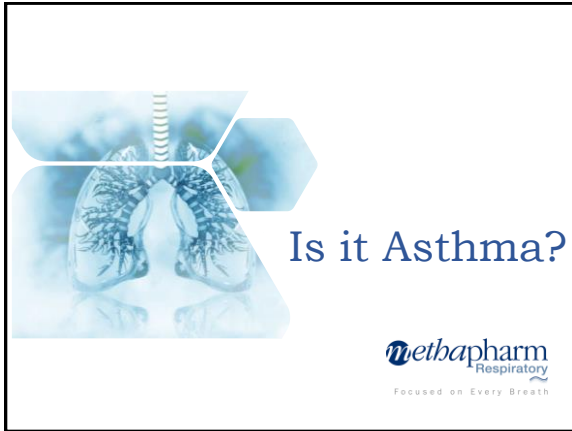




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Disclaimer

Name of presenter: Heather Murgatroyd
Name of employer: Methapharm Respiratory

I recognize that I must follow all guidelines and criteria regarding vested interest. Yes, I have the following real or perceived conflicts of interest that relate to this presentation:

- I am an employee of Methapharm - manufacturer and distributor of Provocholine® and distributor of the Vivatmo pro.

2




2

Objectives

At the conclusion of this presentation the attendee will be able to:

- Discuss prevalence and economic burden of asthma in the United States
- Review common signs & symptoms of, as well as phenotypes of asthma
- Recognize disease states that mimic asthma symptoms
- Discuss and know when to utilize the available objective tests for diagnosing asthma
- Identify and discuss available medications, indications and guidelines pertaining to asthma

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Prevalence

Global

- World Health Organization
 - 262 million have asthma worldwide.
- Global issue
- Prevalence highest among children
- Middle to lower income families have a higher mortality



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Prevalence

USA

- ~28 million Americans have Asthma
- 1 in 13 Americans
- Increasing since 1980's



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Question 1

On average, _____ people die from asthma every day in the USA.

- A. 5
- B. 10
- C. 20
- D. 25



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Question 1



Every day
10 People in the USA die
 from an asthma exacerbation



Every day,
100 People in the world DIE
 from an asthma exacerbation



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Economic Burden of Asthma



Chronic Disease affects:

- Quality of life
- Productivity at work and school
- Use of healthcare resources
- Mortality



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How Much Does Asthma Cost?



2008-2013 – Direct Medical Costs

- 213,994 pooled sample
- 10,237 had treated asthma (at least one medical or pharmaceutical encounter or claim associated with asthma)
- Annual per-person cost \$3,266, 2015 US dollars, or \$50.3 BILLION attributed to:
 - \$1830 / prescription medication
 - \$640 / office visits
 - \$529 / hospitalizations
 - \$176 / hospital-based outpatient visits
 - \$105 / emergency room visits



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How Much Does Asthma Cost?

2008-2013

Losses

- Missed work and school days - **\$3 Billion**
- Asthma-related mortality - **\$29 Billion**
- Medical Cost - **\$50.3 Billion**

Totaling \$82 Billion



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What Impacts Costs?

Factors

- New treatment options
- Federal and state policies
- Price fluctuations
- Healthcare market
- Effectiveness of asthma control programs



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Question 2

The first study of the economic burden of asthma was done in

- A. 1955
- B. 1974
- C. 1987
- D. 1990

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Increasing Economic Burden

The Cost of Asthma



- **1990** first study of economic burden of asthma - **\$6.2 Billion**
 - Direct medical costs and productivity loss due to morbidity and mortality
- **2007** total medical costs - **\$37.2 Billion**
 - \$2,078 / adults, \$1,005/children
- **2011** total national cost - **\$56 Billion**
 - \$3,856 / person

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Costs in Subgroups

Medical Expenditure Panel Survey Data



The total unadjusted medical costs of asthmatics vs non asthmatics, showed asthmatics were more than double the cost (approx. \$3300 per year)

Examples of subgroups with higher per person medical costs:

- Adults (\$3760)
- Medicare (\$3720)
- Below poverty line (\$3581)

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Economic Burden of Asthma

Absenteeism



- Children with asthma missed 13.8 million school days each year
- Adult with asthma missed 14.2 million workdays each year



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Limitations of Study

What wasn't included?

Nonmedical costs:

- Transportation
- Appointment wait time
- Pre-absenteeism
(present but not fully functional at work due to illness)
- Pain and suffering




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So?

Is it asthma?




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Asthma is Not Simply Asthma

Phenotype & Endotype

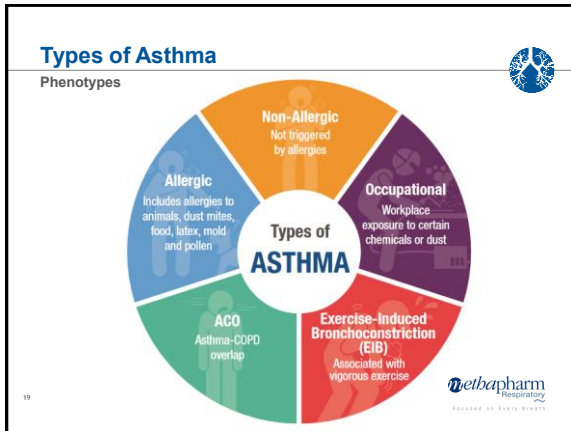
Phenotypes:
The observable properties of an organism that are produced by the interaction of the genotype and the environment

Endotypes:
Are the pathobiological mechanistic pathways that are measurable but unseen by the unaided eye which helps to explain the observable properties of the phenotype.

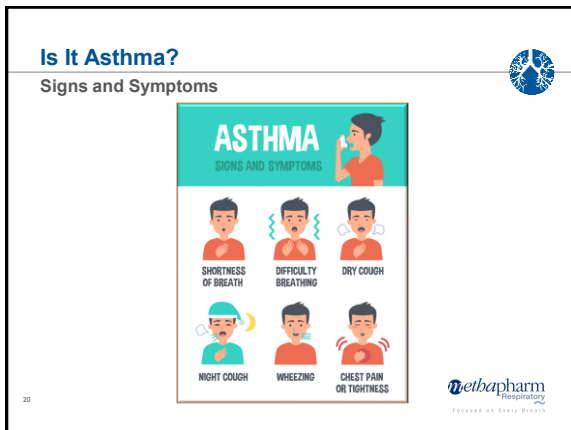


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Diagnosing Asthma

What is being done?

Research found that diagnosis often based on symptoms alone:

- Wheezing
- Shortness of breath
- Cough

The diagram shows two lungs side-by-side. The left lung is labeled 'HEALTHY LUNG' and has clear, open airways. The right lung is labeled 'ASTHMA' and has narrowed, inflamed airways. Above the lungs, the word 'ASTHMA' is written. Below the lungs, the text 'Not confirming diagnosis with objective testing' is written.

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Question 3



68% of asthma diagnosis are confirmed by spirometry

- A. True
- B. False

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Reevaluation of Asthma in Adults



Research shows

2017 a study published in JAMA looked at patients with a current asthma diagnosis

710 patients with a current diagnosis of asthma were selected to participate

- 613 patients completed the entire study
- 56% of those patients did not have objective testing as part of their initial diagnosis
- 203 were found to NOT have asthma

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All that Wheezes is Not Asthma!



Diseases that share symptoms with asthma

- Congestive Heart Failure
- Vocal Cord Dysplasia
- Vocal Cord Paralysis
- Allergies
- GERD / Aspiration
- Sinusitis
- Myocardial Ischemia
- Bronchiectasis
- Tumors
- Pulmonary Aspergillosis



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Question 4



Spirometry is the only objective test available to identify asthma.

- A. True
- B. False



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Test



Spirometry with and without bronchodilator

What is it? A physiological test that measures how an individual inhales or exhales volumes of air as a function of time

Why do it? Valuable as a screening test of general respiratory health, to evaluate symptoms, signs or abnormal laboratory tests, to measure the effect of disease on pulmonary function

How do we do it? three distinct phases to the FVC maneuver:

- 1) maximal inspiration
- 2) a "blast" of exhalation
- 3) continued complete exhalation to the end of test

Is there reimbursement? Yes



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Objective Tests



Patients may respond differently, depending on the type of test

Direct

- Methacholine Challenge Test
- Histamine

Indirect

- Exercise
- Eucapnic Voluntary Hyperventilation
- Mannitol
- Cold air

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Question 5



Direct Challenge Tests

- A. Directly stimulate smooth muscles cells
- B. May cause inflammation
- C. May cause airway hyperresponsiveness
- D. All of the above

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Direct Bronchial Challenge Test



Methacholine Challenge Test

What is it? The administration of methacholine chloride a bronchoconstrictor through a nebulizer that acts directly on the airway smooth muscle.

Why do it? The primary indication is to help determine if current respiratory symptoms may be due to asthma or to make that diagnosis less likely.

How do we do it?

- ✓ Inhalation of increasing concentrations of methacholine.
- ✓ Spirometry is performed 30 and 90 seconds post delivery.
- ✓ FEV₁ is monitored throughout test, watching for a 20% fall from baseline FEV₁.

Is there reimbursement? Yes

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Direct Bronchial Challenge Test



Histamine

What is it? Inhalation of a nebulized solution of histamine. Starting with a low dose and progressing to higher doses.

Why do it? Similar to methacholine, to assist in diagnosis

How do we do it?

- ✓ Inhalation of increasing doses of histamine.
- ✓ Spirometry after each dose looking for a fall of 20% in FEV₁.

Is there reimbursement? Yes

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Question 6



Indirect challenge tests

- A. Are easier to perform than direct challenge tests
- B. Do not require spirometry
- C. Stimulate the release of inflammatory mediators
- D. All of the above

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Indirect Bronchial Challenge Test

Exercise Challenge Test



What is it? Serial spirometry after a specific exercise challenge is to determine if exercise induced bronchoconstriction (EIB) is present and to quantify the severity of the disorder.

Why do it? Ample data showing that EIB occurs commonly in athletes at all levels.

How do we do it?

- ✓ Spirometry after a specific exercise – treadmill or stationary bicycle.
- ✓ FEV₁ is typically measured at 5, 10, 15, and 30 minutes after exercise.

Is there reimbursement? Yes

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Indirect Bronchial Challenge Test

Eucapnic Voluntary Hyperventilation



What is it? Subject completes a period of voluntary hyperpnea with a dry gas inhalant, which desiccates the airways, mimicking the osmotic priming stimulus to EIB.

Why do it? To confirm EIB in athletes. EIB is prevalent in athletes even without an asthma diagnosis

How do we do it?

- ✓ Subject breathes dry gas during challenge.
- ✓ MVV maneuver followed by serial spirometry to assess FEV₁.
- ✓ A drop of ≥10% in FEV₁ constitutes a positive study.

Is there reimbursement? Yes

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Indirect Bronchial Challenge Test



Cold Air Challenge

What is it? Used to diagnose AHR & EIB

Why do it? Patient reports symptoms of EIB but initial spirometry or inhalation challenge tests were negative

How do we do it?

- ✓ Similar method as Exercise or EVH, cooling the air

Is there reimbursement? Yes

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Indirect Bronchial Challenge Test



Mannitol

What is it? Mannitol is a naturally occurring sugar, as a dry powder it is a hypertonic stimulus, causing a drying effect in the airways

Why do it? Standardized challenge used in diagnosing AHR & EIB

How do we do it?

- ✓ The patient inhales increasing doses of mannitol
- ✓ FEV₁ measured 1 minute post delivery
- ✓ Watching for a 15% drop from baseline FEV₁ or a 10% fall between doses of mannitol.

Is there reimbursement? Yes

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Test



Impulse Oscillometry

What is it? An impulse consisting of a mixture of sound waves of different frequencies is generated by a speaker at the mouth.

Why do it? Noninvasive method which to measure respiratory mechanics. Does not require effort by patient, can be performed by patients unable to do spirometry.

How do we do it?

- ✓ Sound waves of varying frequencies are superimposed over normal tidal breathing.

Is there reimbursement? Yes

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Test

Fractional Exhaled Nitric Oxide (FeNO)



What is it? A simple, noninvasive measurement of inflammation in the lung and can be used as a complimentary measurement in managing asthmatic patients.

Why do it? Nitric Oxide (NO) is produced in the lungs and present in exhaled breath. It is an indication of inflammation in the lung.

How do we do it?

- ✓ Simple, noninvasive single, slow – steady exhaled breath measurement.

Is there reimbursement? Yes

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Medications

Alphabet Soup



- SABA
- SAMA
- LAMA
- LABA
- LTRA
- Combo Meds:
 - ICS/LABA
 - ICS/LABA/LAMA
- Biologics



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Managing Asthma

GINA recommendations



Global Initiative for Asthma (GINA)

- 3 months stable asthma
- Step down meds
- Safe and practical approach



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Managing Asthma

ATS



Control means manifestations of asthma are reduced/removed with treatment.

Emphasizing:

- Level of control decreases symptoms and allows ADLs to achieve optimum quality of life.
- Minimize future risk of losing control - avoid exacerbations, and accelerated decline in lung function.
- Decrease exposure to side effects of tx.

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Managing Asthma

ATS



How do we gain better control?

- Increase awareness of asthma guidelines
- Recognize and teach signs and symptoms
- Mitigate future risk



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Managing Asthma

Consequences of inappropriate treatment



- Quality of life
- Cost of medication
- Side effects
- Psychological effects
- Economic burden



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Are you sure it is Asthma?



Total cost of asthma

\$82 BILLION

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Is It Asthma?

Summary



- Asthma has signs and symptoms shared with many disease states
- Asthma prevalence is continuing to grow
- Medications are becoming increasingly specific
- There are multiple phenotypes of asthma
- Objective testing may help reduce the number of patients misdiagnosed, underdiagnosed or over-diagnosed with asthma

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Questions?



thank you!

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