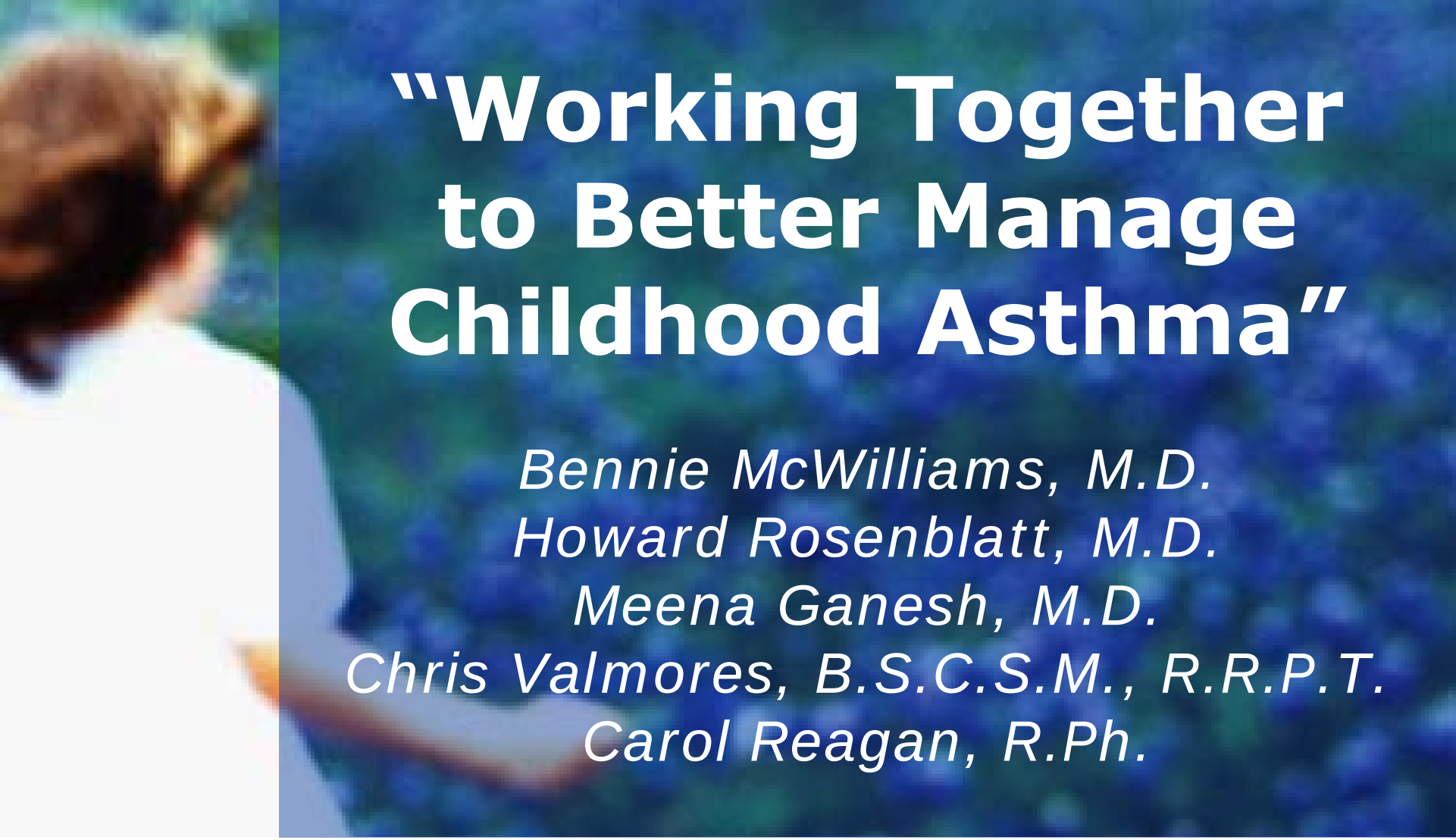

"Working Together to Better Manage Childhood Asthma"

Bennie McWilliams, M.D.
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Meena Ganesh, M.D.
Chris Valmores, B.S.C.S.M., R.R.P.T.
Carol Reagan, R.Ph.

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Johnny Smith

- Johnny is a 5 year old boy who presented to your clinic for the first time on Friday afternoon at 3:00pm
- He presents to your office with a history of increased work of breathing and wheezing

Johnny Smith – Past Medical History

- Multiple Ear infections
- Recurrent sinus infections
- Eczema

Johnny Smith – Current Medications

- Fluticasone MDI 44 mcg (Flovent 44) 2 inhalations BID – he uses this only intermittently
- Singulair 5 mg once daily in the morning
- Albuterol nebulizer as needed – uses about 2-3 times daily on average

Johnny Smith – Physical Exam

- VS HR 160 RR 50 O2 sats 96 % RA
- O/E HEENT Nasal flaring
- Allergic shiners +
- Cobblestoning+ w/ purulent postnasal drainage
- Neck Supple
- RS Fair air entry bilaterally
- Wheezing throughout
- I:E 1:3
- CVS S1S2 normal no murmurs
- Skin Eczema on the extremities
- Rest of the exam unremarkable

Johnny Smith

- What is your next step?
- You choose to give albuterol 2.5mg by nebulizer
- After the albuterol Johnny has the following exam:
  - Oxygen sats 89%
  - Still wheezing, tachypneic
- What's gong on and what's next?

Johnny Smith

- Arrangements are made to admit the patient to Dell Children's Hospital
- You contact Dr. Ganesh who assumes care of the patient
- He is placed on the asthma pathway
- After 24 hours he is off oxygen and ready for discharge
- What role does an asthma pathway have in the hospital course?

Johnny Smith

- What medications would you discharge Johnny home on?
- What type of asthma education would this patient benefit from now and in the outpatient setting
- What follow-up would you plan?

Johnny Smith – Follow-up

- You see Johnny back in 2 weeks.
- His asthma is better
- However, he is still having allergy symptoms although his mother does not feel they are causing any significant problems
- What role do allergies play in his asthma?

Johnny Smith

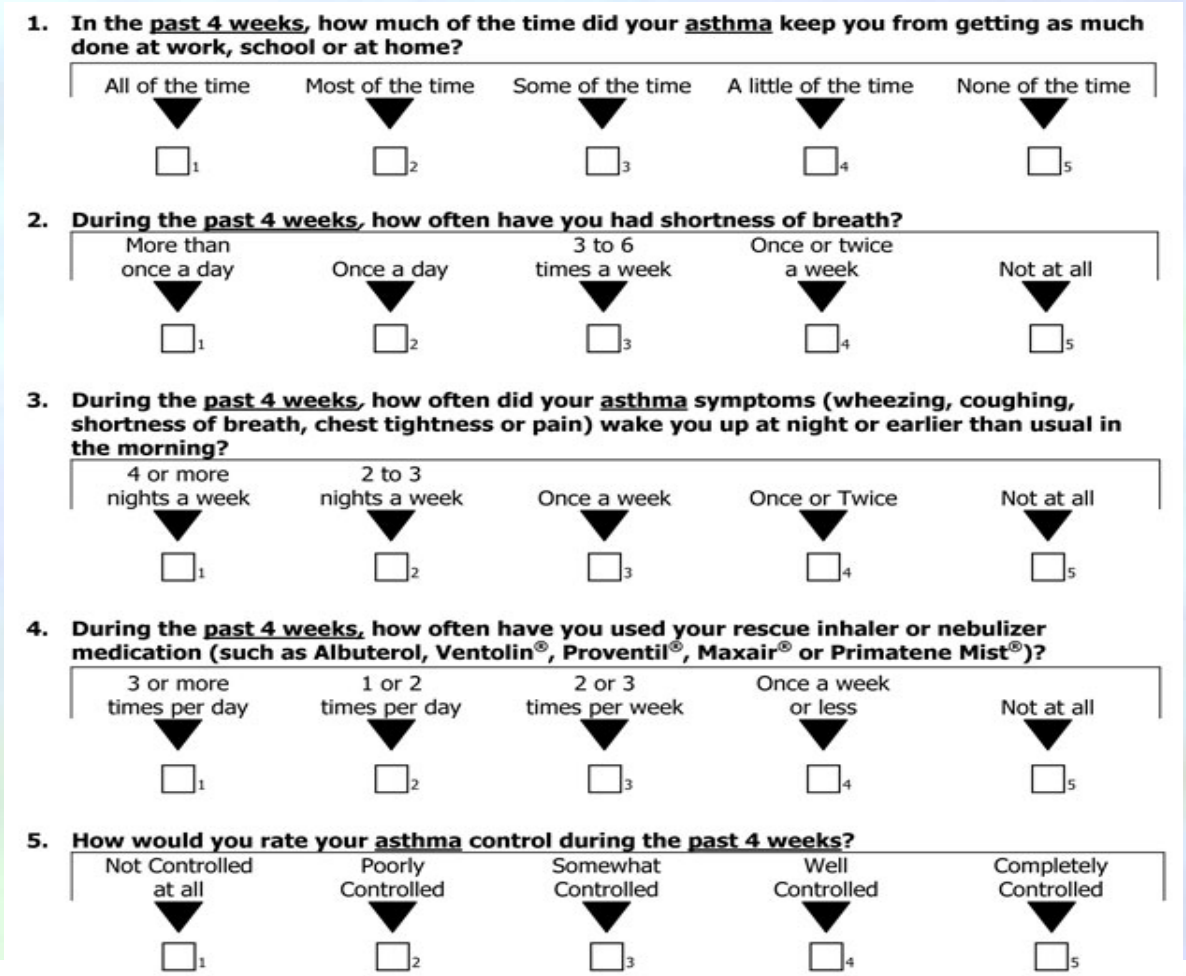
- Johnny is seen back in 1 month.
- He is using his albuterol inhaler twice daily on average and has nocturnal symptoms about twice a week
- How do you classify asthma severity and assess control?
- What are the approaches based on the new NHLBI guidelines that might assist you in the management of this patient?

Johnny Smith

- Johnny returns in 6 months.
- His asthma is controlled on Advair 100/50 1 inhalation twice daily
- His asthma control test is 22.

  What is the asthma control test?
- His parents have read that patients taking Advair are dying from their asthma and patients taking Singulair are all committing suicide and want to discontinue all medications.

Asthma Control Test



1. **In the past 4 weeks, how much of the time did your asthma keep you from getting as much done at work, school or at home?**

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐1	☐2	☐3	☐4	☐5

2. **During the past 4 weeks, how often have you had shortness of breath?**

More than once a day	Once a day	3 to 6 times a week	Once or twice a week	Not at all
☐1	☐2	☐3	☐4	☐5

3. **During the past 4 weeks, how often did your asthma symptoms (wheezing, coughing, shortness of breath, chest tightness or pain) wake you up at night or earlier than usual in the morning?**

4 or more nights a week	2 to 3 nights a week	Once a week	Once or Twice	Not at all
☐1	☐2	☐3	☐4	☐5

4. **During the past 4 weeks, how often have you used your rescue inhaler or nebulizer medication (such as Albuterol, Ventolin®, Proventil®, Maxair® or Primatene Mist®)?**

3 or more times per day	1 or 2 times per day	2 or 3 times per week	Once a week or less	Not at all
☐1	☐2	☐3	☐4	☐5

5. **How would you rate your asthma control during the past 4 weeks?**

Not Controlled at all	Poorly Controlled	Somewhat Controlled	Well Controlled	Completely Controlled
☐1	☐2	☐3	☐4	☐5

Level of Control Based on Composite Score2

≥20 = Well Controlled

16-19 = Not Well Controlled

≤15 = Very Poorly Controlled

Regardless of patient's self-assessment of control in Question 5

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Johnny Smith

- Johnny returns in 6 months.
- His asthma is controlled on Advair 100/50 1 inhalation twice daily
- His asthma control test is 22.

- His parents have read that patients taking Advair are dying from their asthma and patients taking Singulair are all committing suicide and want to discontinue all medications.

Johnny Smith

- In response, you tell his mother one of the following:
- She should not be reading so much
- You are the doctor and know what's right
- She should seek medical care for Johnny elsewhere
- You explain the risks and benefits of all the medications and work out a treatment program that is medically sound and addresses her concerns

Johnny Smith

- In response, you tell his mother one of the following:
- She should not be reading so much
- You are the doctor and know what's right
- She should seek medical care for Johnny elsewhere
- You explain the risks and benefits of all the medications and work out a treatment program that is medically sound and addresses her concerns

Johnny Smith

- After this visit, Johnny's mother stops all his maintenance medications
- He has progressively increasing asthma symptoms and uses his albuterol 3 times a day on average
- 3 weeks later he has a severe asthma episode and is hospitalized requiring PICU therapy
- Where did you go wrong?

Update on National Asthma Education and Prevention Program (NAEPP) Guidelines for the Treatment of Asthma

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Asthma Is Prevalent: Significant Morbidity and Mortality

32.6 Million People Have Had an Asthma Diagnosis in Their Lifetime

22.2 Million People Are Currently Diagnosed With Asthma

12.2 Million People Suffer From Asthma Attacks Annually

Approximately 4000 Asthma-Related Deaths Occur Annually

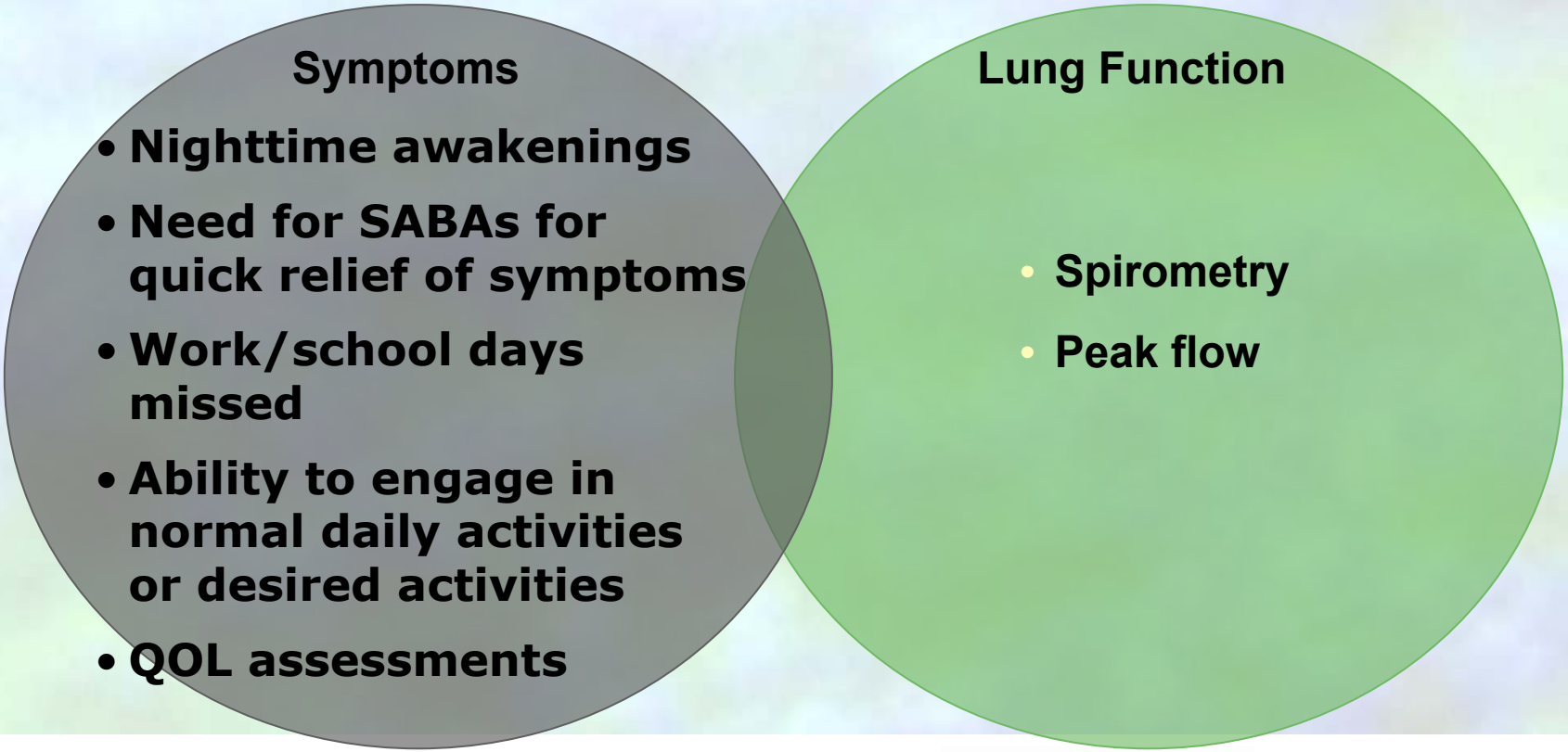
Approximately 11 People Die From Asthma Each Day

Asthma Assessment and Monitoring: Key Differences From 1997 and 2002 Expert Panel Reports

- Key elements of assessment and monitoring
  - Severity
  - Control
  - Responsiveness to treatment
- Severity emphasized for initiating therapy
- Control emphasized for monitoring and adjusting therapy
- Severity and control defined in terms of 2 domains
  - Impairment
  - Risk

Assessing Asthma Severity: Impairment Domain

Impairment = Frequency and Intensity of Symptoms and Functional Limitations



Assessing Asthma Severity: Risk Domain

- **Likelihood of asthma exacerbations, progressive decline in lung function, or risk of adverse effects from medications**
- **Assessment**
  - **Frequency and severity of exacerbations**
  - **Oral corticosteroid use**
  - **Urgent-care visits**
  - **Lung function**
  - **Noninvasive biomarkers may play an increased role in future**

Goal of Asthma Therapy: Achieve Control

Reduce Impairment

- Prevent chronic and troublesome symptoms
- Require infrequent use of inhaled SABA (≤2 days/week)
- Maintain (near) "normal" pulmonary function
- Maintain normal activity levels
- Meet patients' expectations of, and satisfaction with, asthma care

Reduce Risk

- Prevent recurrent exacerbations
- Minimize need for emergency department visits or hospitalizations
- Prevent progressive loss of lung function
- Provide optimal pharmacotherapy, with minimal or no adverse effects

Periodic Assessment of Asthma Control Recommended (1- to 6-month intervals)

- Are goals of therapy being met?
- Are adjustments in treatment necessary?
- Measure
  - Signs and symptoms
  - Pulmonary function
  - QOL/functional status
  - History of exacerbations
  - Pharmacotherapy
  - Patient-provider communication and patient satisfaction

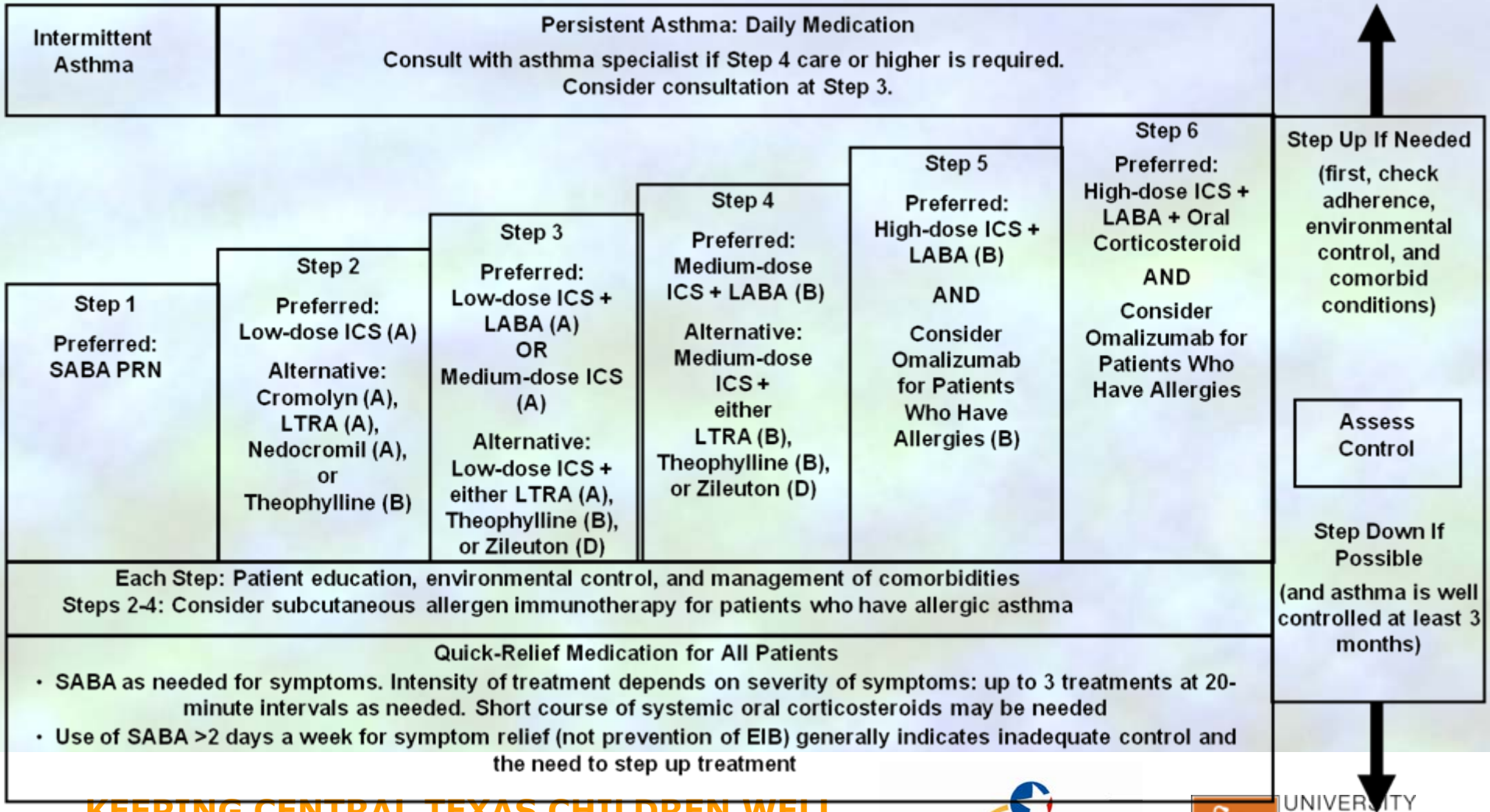
Classifying Asthma Severity and Assessing Asthma Control

- **In patients not on long-term controller medications**
  - Severity based upon domains of impairment and risk
  - Level of severity based upon most severe category in which any feature appears
- **In patients on long-term controller medications**
  - Severity based upon lowest step required to maintain clinical control
  - Control of asthma based upon domains of impairment and risk
    - Level of control based upon most severe impairment or risk category
    - Validated questionnaires may be used in patients aged ≥12 years

Classifying Asthma Severity and Initiating Treatment in Youths ≥12 Years of Age and Adults

Components of Severity		Intermittent	Persistent		
			Mild	Moderate	Severe
Impairment Normal FEV1/FVC: 8-19 yr 85% 20-39 yr 80% 40-59 yr 75% 60-80 yr 70%	Symptoms	≤2 days/week	>2 days/week but not daily	Daily	Throughout the day
	Nighttime awakenings	≤2x/month	3-4x/month	>1x/week but not nightly	Often 7x/week
	SABA use for symptom control (not prevention of EIB)	≤2 days/week	>2 days/week but not daily and not more than 1x on any day	Daily	Several times per day
	Interference with normal activity	None	Minor limitation	Some limitation	Extremely limited
	Lung Function	• Normal FEV1 between exacerbations • FEV1 >80% predicted • FEV1/FVC normal	• FEV1 >80% predicted • FEV1/FVC normal	• FEV1 >60% but <80% predicted • FEV1/FVC reduced 5%	• FEV1 <60% predicted • FEV1/FVC reduced >5%
Risk	Exacerbations requiring oral systemic corticosteroids	0-1/year	≥2/year →		
		← Consider severity and interval since last exacerbation →			
		Frequency and severity may fluctuate over time for patients in any severity category			
		Relative annual risk of exacerbations may be related to FEV1			
Recommended Step for Initiating Treatment		Step 1	Step 2	Step 3	Step 4 or 5
				and consider short course of oral systemic corticosteroids	
		In 2 to 6 weeks, evaluate level of asthma control that is achieved and adjust therapy accordingly			

Stepwise Approach for Managing Asthma in Patients Aged ≥12 Years



Assessing Asthma Control and Adjusting Therapy in Youths ≥12 Years of Age and Adults

Components of Control		Well Controlled	Not Well Controlled	Very Poorly Controlled
Impairment	Symptoms	≤2 days/week	>2 days/week	Throughout the day
	Nighttime awakenings	≤2x/month	1-3x/week	≥4x/week
	Interference with nl activity	None	Some limitation	Extremely limited
	SABA use for symptom control (not prevention of EIB)	≤2 days/week	>2 days/week	Several times per day
	FEV1 or peak flow	>80% predicted/ personal best	60%-80% predicted/ personal best	<60% predicted/ personal best
	Validated questionnaires ATAQ ACQ ACT	 0 ≤0.75 ≥20	 1-2 ≥1.5 16-19	 3-4 N/A ≤15
Risk	Exacerbations requiring oral systemic corticosteroids	0-1/year	≥2/year	
		Consider severity and interval since last exacerbation		
	Progress loss of lung function	Evaluation requires long-term follow-up		
	Treatment-related adverse effects	Medication side effects can vary in intensity from none to very troublesome and worrisome. The level of intensity does not correlate to specific levels of control but should be considered in the overall assessment of risk		
Recommended Action for Treatment		• Maintain current step • Regular follow-ups every 1-6 months to maintain control • Consider step down if well controlled for at least 3 months	• Step up 1 step and • Reevaluate in 2 to 6 weeks • For side effects, consider alternative treatment options	• Consider short course of oral systemic corticosteroids • Step up 1-2 steps, and • Reevaluate in 2 weeks • For side effects, consider alternative treatment options

Conclusions

- Severity, control, and responsiveness to treatment are key elements of asthma assessment and monitoring
- The goal of asthma therapy is to achieve control based on NAEPP guidelines
- Clinical assessment and patient self-assessment are primary methods for monitoring asthma control
- ICS is preferred monotherapy to help achieve asthma control in patients with persistent asthma
- LABAs are preferred adjunctive agents in patients aged ≥12 years who cannot be controlled with ICS monotherapy

Johnny Smith –
get back to him

- After this visit, Johnny's mother stops all his maintenance medications
- He has progressively increasing asthma symptoms and uses his albuterol 3 times a day on average
- 3 weeks later he has a severe asthma episode and is hospitalized requiring PICU therapy
- What compliance issues are to be addressed?

ASTHMA:
An Overview of Therapy & Barriers to Adherence

Carol Reagan, Pharm.D.

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How is asthma controlled?

- Identification of triggers
- Self-assessment forms
- Symptoms diary
- Monitoring: peak flow meters, asthma action plans, periodic clinical assessments, PFTs
- Pharmacotherapy

Pharmacotherapy

- Short-acting treatment
  - Short-acting B_2 agonists
  - Anticholinergics
  - Systemic corticosteroids in bursts
- Long-acting treatment
  - Inhaled/systemic steroids
  - Leukotriene modifiers
  - Long-acting B_2 agonists
  - Methylxanthines
  - Anti-inflammatory & mast cell modulators
  - Anticholinergics
  - Anti-IgE

Pharmacotherapy

- Short-acting Rxs
  - B_2 agonists: albuterol, levalbuterol, pirbuterol
  - Anticholinergics: ipratropium
  - Corticosteroids: methylprednisilone, prednisolone, prednisone
- Provide prompt relief
- DOC for managing acute exacerbations, preventing exercise-induced asthma
- Frequency of use = a barometer of disease activity

Pharmacotherapy

- **Short-acting medications**
  - Adverse effects: nervousness, “jitters”, insomnia, hypokalemia, arrhythmias
  - Regularly scheduled dosing not recommended
  - Bad taste/spacers
  - Available in metered-dose inhalers, tablets, liquids
  - Increased use associated with uncontrolled asthma & increased risk of death

Pharmacotherapy

- **Long-acting Rxs**
  - Inhaled steroids: budesonide, flunisolide, fluticasone, mometasone, triamcinolone, beclomethasone
  - Systemic steroids
  - Combos
  - Anti-IgE

- **Long-acting Rxs**
  - Cromolyn sodium
  - Nedocromil
  - Long-acting B_2 agonists
  - Methylxanthines
  - leukotrienes

Pharmacotherapy

- **Inhaled corticosteroids**
  - Long-term prevention of symptoms & suppression,control & reversal of inflammation
  - Available in sprays or powders
- **Adverse effects**
  - Sore throat, thrush, hoarseness
  - Taste
  - Systemic side effects
  - Spacers
  - Rinse mouth after use
  - Lowest possible dose

Pharmacotherapy

- **Systemic steroids**
  - Long-term prevention in severe, persistent asthma and suppression, control & reversal of inflammation
  - Available in tablets or liquids
- **Adverse effects**
  - Adrenal/growth suppression, dermal thinning, HTN, diabetes, Cushing's syndrome, cataracts, muscle weakness, impaired immune system
  - Mood swings, hyper-activity, dependence, weight gain, osteoporosis

Pharmacotherapy

- **Cromolyn sodium & nedocromil**
  - Long-term prevention of symptoms
  - Mild to moderate anti-inflammatory activity
  - Mast cell inhibitors
  - Use in children
- **Adverse effect**
  - Few side effects
  - Bad taste
  - QID dosing
  - May take 2-5 weeks to become therapeutic
  - Cromolyn < effective for bronchospasm than nedocromil

Pharmacotherapy

- **Long-acting B2 agonists & combos**
  - Long-term prevention of symptoms, particularly nocturnal
  - Prevention of exercise-induced asthma
  - Sprays or dry-powder
- **Adverse effects**
  - NOT FOR ACUTE RELIEF
  - Tachycardia, skeletal muscle tremor, hypo-kalemia, QT interval prolongation in overdose
  - NOT used to replace anti- inflammatory therapy
  - Black Box Warning

Pharmacotherapy

- **Methylxanthines**
  - Long-term control & prevention of symptoms, especially nocturnal
  - Available in liquids, sustained-relief tablets & capsules
  - Some formulations being discontinued
  - Monitoring of levels
- **Adverse effects**
  - Tachycardia, N/V, CNS stimulation, arrhythmias, HA, seizures, hyper-glycemia, hypo-kalemia, insomnia, difficulty in urination
  - DRUG INTERACTIONS
  - Diet, smoking, charcoal

Pharmacotherapy

- **Leukotriene modifiers**
  - Long-term control & prevention of symptoms in mild, persistent asthma
  - NOT for acute relief
- **Adverse effects**
  - Drug interactions with warfarin, theophylline
  - Competitive inhibition of P450 enzymes
  - Elevation of liver enzymes
  - Eosinophilic vasculitis - be alert to rashes
  - Chewable tablets contain phenylalanine

Pharmacotherapy

- **What's new?**
  - Omalizumab (Xolair) - anti-immunoglobulin E
  - Administered bi-weekly/monthly by injection
  - Reduces the level of IgE in the body & prevents allergic response
  - Studies show prevention of both early & late phase asthmatic response
  - Expensive!

What else?

- Nasal sprays
- Anti-histamines
- Bedding
- Pets
- Air filters
- Carpeting
- Seasonal allergies
- Scents
- Smoking
- Education

What is the pharmacist's role in controlling asthma?

- Know & use the national guidelines
- Communicate with & educate the patient, the caregiver & other healthcare providers
- Monitor medication use & refills
- Provide educational resources
- Increase adherence through cooperation, setting goals, teaching management tools

Factors Affecting Adherence

- Patient/health professional interactions
- Literacy levels
- Inability to understand importance of therapy & consequences of non-adherence
- Poor understanding of verbal instructions
- Patient uses multiple physicians/pharmacies
- Age
- Lack of support
- Culture/religion
- Economics

So what do we do….?

- STOP
- LOOK
- LISTEN

STOP

- What do I know about this patient?
- How often do I see him?
- Have I seen her inhaler technique?
- Is a caregiver involved?
- Have I provided educational materials/resources?
- Do peak flow readings = reported adherence?
- Is the patient refilling "rescue" inhalers, but not maintenance Rxs?
- How often is he refilling the "rescue" inhaler?

LOOK

- **Are there drug therapy problems?**
  - **ADRs**
  - **Drug interactions**
  - **Dosage too high/low**
  - **Need additional drug therapy**
  - **Wrong drug for patient**
  - **Inappropriate adherence**
  - **“Rule of 2’s”**

LISTEN

- **Communicate with patients**
  - **Basic facts about asthma**
  - **Roles & importance of medications**
  - **Skills**
  - **Environmental triggers**
  - **Action plans & symptom diaries**
  - **Ask questions**
  - **Listen to the answers**

- **"The issue is really not what to do, but rather how to get done what we know should be done."**

  –Stephen C. Lazarus, MD