individualized dynamic phenotyping-for improved asthma control

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Pediatric Pulmonologist
Director of Allergy and Asthma Research
Lifestyle change advocate
Dean Medical Center
Madison, WI

Defining Disease Control in Asthma Is Difficult

<table>
<thead>
<tr>
<th>Oncology</th>
<th>Asthma</th>
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<tr>
<td>Disease-free survival, tumor recurrence or growth</td>
<td>Symptoms?</td>
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</table>

| Diabetes mellitus                                                        |                                                                      |
|                                                                        | Serum glucose                                                        |
|                                                                        | Hemoglobin A1C                                                       |

| Rheumatoid arthritis                                                    |                                                                      |
|                                                                        | Composite disease scores                                             |
|                                                                        | X-ray progression                                                    |

Diseases Asymptomatic Symptomatic Severe event

<table>
<thead>
<tr>
<th>Diseases</th>
<th>Asymptomatic</th>
<th>Symptomatic</th>
<th>Severe event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>↑BP</td>
<td>↑Blood Chol</td>
<td>Stroke</td>
</tr>
<tr>
<td>Coronary heart disease</td>
<td>↑Blood Trig</td>
<td>↑Blood LDL</td>
<td>Myocardial infarction</td>
</tr>
<tr>
<td>Diabetes</td>
<td>↑Blood sugar</td>
<td></td>
<td></td>
</tr>
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</table>

Asthma

- AHR
- PEF variation
- NO
- Allergic rhinitis

Early intervention (Secondary prevention)

More preventable and controllable?
Defining Disease Control in Asthma Is Difficult

- **Oncology**
  - Disease-free survival
  - Tumor recurrence or growth

- **Diabetes mellitus**
  - Serum glucose
  - Hemoglobin A1C

- **Rheumatoid arthritis**
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  - X-ray progression

- **Asthma**
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  - Exacerbations?
  - Exercise tolerance?
  - Exhaled nitric oxide?
  - Sputum eosinophils?

FEV1: forced expiratory volume in 1 second, PEF: peak expiratory flow.

What Should we Mean by “Control”?

ACT

Bursts of Oral Steroids

FEV1

FeNO

PBL CASE

A.K. is a 16 year-old young woman who has just arrived to your city due to her parents’ job transfer, presents to your office for an evaluation of her asthma. They report that she has had asthma most of her life with several hospitalizations and ER visits mainly as a toddler, but has still required 2-3 courses of oral steroids per year until the last two years.

The last two years, her parents felt that she has done well after switching to budesonide/formoterol 80/4.5, 2 puffs twice daily. She needs refills on her medication and wonders whether she can safely lower her medications.
SO, THE QUESTIONS ARE...

1. **How do we best assess whether or not she is well controlled?**

2. **What tools can we utilize to predict whether or not stepping down her therapy would be successful?**
Functional status?

Missed work and/or school?

Nighttime awakenings?

Lung function?

Daytime symptoms?

Nighttime awakenings?

Use of “quick-reliever”?

Patient self-report of control?

Utilization of health care resources?

Satisfaction with care?

Functional status?

Missed work and/or school?

Heterogeneity of Response: What Response?—What is Control?

Necessary to Good Asthma Care

• Accurate diagnosis
• Appropriate choice of therapy
• Control of Comorbidities
• Adequate drug delivery and Adherence
• Monitoring Impairment and risk assessment
### The Goal for Treating Asthma has Shifted to Achieving Control

<table>
<thead>
<tr>
<th>Reduction in Impairment</th>
<th>Reduction in Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>➢ Minimal (ideally, no) troublesome symptoms</td>
<td></td>
</tr>
<tr>
<td>➢ No rescue medications needed</td>
<td></td>
</tr>
<tr>
<td>➢ No nighttime awakenings due to symptoms</td>
<td></td>
</tr>
<tr>
<td>➢ (Near) normal pulmonary function</td>
<td></td>
</tr>
<tr>
<td>➢ Normal daily activities</td>
<td></td>
</tr>
<tr>
<td>➢ Minimal (ideally, no) symptom exacerbations</td>
<td></td>
</tr>
<tr>
<td>➢ No urgent care (unscheduled office visits, ED visits, hospitalizations)</td>
<td></td>
</tr>
<tr>
<td>➢ Minimal (ideally, no) adverse events from pharmacotherapy</td>
<td></td>
</tr>
</tbody>
</table>

### Risk: Assessing Control

<table>
<thead>
<tr>
<th>Risk</th>
<th>Classification of Asthma Control</th>
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<tr>
<td></td>
<td>Well-Controlled</td>
</tr>
<tr>
<td>Exacerbations</td>
<td>0–1 per year</td>
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### Measuring Asthma Control (NAEPP 2007)

<table>
<thead>
<tr>
<th>Component of Control</th>
<th>Well-Controlled</th>
<th>Not Well-Controlled</th>
<th>Very Poorly Controlled</th>
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<tbody>
<tr>
<td>Symptoms</td>
<td>≤ 2 days/wk</td>
<td>&gt; 2 days/wk</td>
<td>Through day</td>
</tr>
<tr>
<td>Nighttime awakenings</td>
<td>≤ 2x/ mo</td>
<td>&gt; 2x/wk</td>
<td>≥ 4x/wk</td>
</tr>
<tr>
<td>Activity interference</td>
<td>None</td>
<td>Some</td>
<td>Extreme</td>
</tr>
<tr>
<td>SABA (not for EIB)</td>
<td>≤ 2 days/wk</td>
<td>&gt; 2 days/wk</td>
<td>Several x/day</td>
</tr>
<tr>
<td>FEV₁ or PEF</td>
<td>&gt;80% Predicted</td>
<td>60-80% Predicted</td>
<td>&lt;60% Predicted</td>
</tr>
<tr>
<td>Exacerbations*</td>
<td>&gt;0-1 yr</td>
<td>&gt; 2 yr</td>
<td>≥ 2 yr</td>
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*Patients with ≥2 exacerbations requiring oral steroids in past yr may be considered as “not-well-controlled,” even in absence of impairment levels consistent with “not-well-controlled” asthma.
Current Available Tools

- **History**
  - Variable between clinicians, patient and time
  - Accuracy in diagnosis good, in others good-to-poor
- **Physical Exam**
  - Helps evaluate comorbidities; otherwise useless
- **Lung Function**
  - Helps diagnosis
  - Somewhat predictive of response to therapy
  - Poorly predictive of exacerbations and other outcomes

Current Available Tools

- **BHR**
  - Correlates well with diagnosis
  - Correlates somewhat with response to therapy
  - Correlates somewhat with risk assessment and monitoring
  - Impractical
- **Sputum eosinophils**
  - Correlates somewhat with diagnosis
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*Patients with ≥2 exacerbations requiring oral steroids in past yr may be considered as “not-well-controlled,” even in absence of impairment levels consistent with “not-well-controlled” asthma.

NHLBI. NAEPP EPR-3: Guidelines for the Diagnosis and Management of Asthma, 2007
Asthma Control Test® (ACT)

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? Score
   - All of the time
   - Most of the time
   - Some of the time
   - A little of the time
   - None of the time

2. In the past 4 weeks, how often have you had shortness of breath?
   - More than once a day
   - Once a day
   - 2-6 times a week
   - 1-2 times a week
   - Not at all

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 in the morning?
   - 4+ nights a week
   - 2-3 nights a week
   - Once a week
   - Once or twice
   - Not at all

4. During the past 4 weeks, how often have you used your rescue inhaler or nebulizer medication (such as albuterol)?
   - 3+ times per day
   - 1-2 times per day
   - 2-3 times per week
   - Once per week or less
   - Not at all

5. How would you rate your asthma control over the past 4 weeks?
   - Not controlled at all
   - Poorly controlled
   - Somewhat controlled
   - Well controlled
   - Completely controlled

Patient Total Score: 24

---

Exhaled Nitric Oxide (eNO) in Asthma

- 1<sup>st</sup> noninvasive marker for airway inflammation
- Elevated in untreated asthma and correlates with peripheral markers of allergic inflammation and airway hyperresponsiveness
- Reduced with anti-inflammatory treatment and predictive of FEV<sub>1</sub> response to ICS
- May help to diagnose asthma in preschool children


---

Clinical Use of eNO

- Accurate Diagnosis
- Treatment Decisions
  - ICS responsiveness
  - ICS dosing
- Treatment Monitoring
  - Document response to ICS
  - Evaluate compliance
  - Predict exacerbation
How Did Monitoring FeNO Improve Care?

1. Serial monitoring of FeNO helpful in assessing response to both oral and inhaled steroid therapy (significant drop following prednisone in April). Normalization and persistence of normal levels while receiving medium dose ICS.

2. More important, serial monitoring was helpful in determining level of adherence with ICS therapy (low eNO levels when therapy monitored by home nurse, increase in levels once that intervention DC'd).

Martin et al., JACI 2007;119:73-80.

Use of Exhaled Nitric Oxide Measurement to Identify a Reactive, at-Risk Phenotype among Patients with Asthma – Dweik et al, 2010

- Study funded by NHLBI, Severe Asthma Research Program - multicenter
- Asthma pts with high eNO were more likely to have been in ED & more likely to have had an ICU admit
- Non-severe asthmatics with high eNO also had increased ER visits and ICU admits

*While the retrospective nature of our analysis has precluded us from determining whether FeNO could predict future risk of exacerbations in asthma, it correlation with ER visits and hospital and ICU admission suggest a great potential for FeNO.*

Fractional Exhaled Nitric Oxide (FENO) Marker of Persistent Lung Inflammation

EXTRA STUDY

Analysis of covariance on log transformed data
Role of eNO in Clinical Practice

- Data to date indicates utility of measure
- More data is needed about utility in a clinical/real world setting
- Data will never be collected without a mechanism of payment and reimbursement
- Data to date indicates utility of measure
- DUH

All scientific work is incomplete, liable to be modified by advancing knowledge. That does not confer freedom to ignore knowledge we have, or postpone action it appears to demand at the given time.


Control Assesses How Close Current Treatment Gets a Patient to Goal

For all patients with asthma, the goal of treatment is the same...optimal asthma control. The difference between patients is the intensity of therapy necessary to get there.
Comorbidities

In the step down therapy of the asthmatic patient consider:

- Upper airway disease (sinusitis and allergic rhinitis)
- COPD/chronic bronchitis
- Smoking
- GERD
- Obesity
- Vocal cord dysfunction
- Obstructive sleep apnea/disorders
- Depression

Depression and Nonadherence

- Depressed patients are 3 times more likely to be nonadherent with medical treatments

Screen for Depression

During the past month:
1. Have you often been bothered by feeling down, depressed, or hopeless?
2. Have you often been bothered by having little interest or pleasure in doing things?


Depression Indicators

*P < 0.05 (Chi-square)

Phenotype Action Plan is your Tools for following asthma control and therapy

- Patient instrument
- Personalized
- Asthma control tools- where and when
- Actions based on symptoms and phenotype
- When and how to get help
- Influence on outcomes controversial because did not include adjustments for phenotype

Nonpharmacologic Therapy to Manage Asthma

- Smoking Cessation
- Patient Education
- Vaccination
- Exercise Rehabilitation
- Diet and Nutrition
- Small Group Therapy/Lifestyle change

Diagnosing Asthma: Comparisons between Exhaled Nitric Oxide Measurements and Conventional Tests – Smith et al, 2004

- Conventional tests are markers of airflow obstruction; eNO is a surrogate biomarker of eosinophilic inflammation
- eNO will measure eosinophilic activity before symptoms are reported and before airway obstruction is detected in spirometry
- eNO is an early indicator of allergic asthmatics inflammation status

Use of Exhaled Nitric Oxide Measurements to Guide Treatment in Chronic Asthma – Smith et al, 2005

- Exhaled NO can be used to reduce ICS dose without compromising asthma control
- ICS reduced by more than 40%
- Despite reduction in dose, asthma exacerbations were less frequent in the eNO group (↓45%)
- Conclusion: Use of eNO to titrate steroid dose could have an impact on cost effectiveness of asthma treatment
The Use of Fraction of Exhaled Nitric Oxide in Pulmonary Practice – Lim et al, 2008

- An elevated FeNO value is helpful in correct diagnosis of asthma in patients
- In presence of respiratory symptoms, elevated FeNO has high sensitivity and specificity for diagnosis
- Only test for airway inflammation performed conveniently and serially at point of care service
- Provides information that is predictive of future disease status

Exhaled Nitric Oxide in Pediatric Asthma – Dinakar, 2009

- Objectively and subjectively describes use of eNO in pediatric asthma management
- Due to advances in technology eNO is a noninvasive, reproducible measurement of eosinophilic airway inflammation, easily performed and a necessary adjunct in asthma practices
- Excellent surrogate marker of eosinophilic airway inflammation, eNO enables clinicians to identify steroid-sensitive patients, monitor steroid response, titrate optimal steroid dose, and monitor steroid compliance at point-of-care.

Consequence of Uncontrolled Asthma!

- Lifestyle limitations
  - Restrictions on daily activities
- Experience long-term symptoms
- Require reliever medication
- Comorbid conditions
  - 49% have psychiatric morbidity (29% depression)
- Lost productivity
  - 10-fold increase in school days lost
  - 40-fold increase in lost work days
- Increased costs
  - Total costs are doubled in uncontrolled patients
  - Costs higher even among patients w/ best supportive care

NAEPP Goals of Asthma Therapy*

– Reduce, eliminate day and night symptoms
– Reduce, eliminate exacerbations
– No limitations on activity
– No effect on school or work
– Maintain (near) normal pulmonary function
– Minimize use of short-acting β₂-agonists (SABAs)
– Minimal adverse effects of asthma medications
– They forgot a big ONE- SELF-EFFICACY

*Adapted from National Asthma Education and Prevention Program Guidelines Update, 2002.

“Gold Standard” Therapy

• Available for 30 years
• Dose response
  – Virtually no information for 25 years
  – Incomplete information for last five
  – Guidelines poorly reflect current knowledge
• Responders/Non-responders
  – Poorly appreciated
  – Very poorly understood
• Side-effects
  – Not common but at-risk group poorly identified
• Compliance
  – Generally poor
  – Optimal delivery method unclear

Necessary to Good Asthma Care

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  – ICS responsiveness
  – ICS dosing
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  – Document response to ICS
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  – Predict exacerbation
eNO equal to bronchial biopsies

Van den Toorn et al, AJRCCM 2001
symptomatic (o) asymptomatic (•) Payne et al, AJRCCM 2001

eNO and accurate diagnosis

Malmberg et al, Thorax 2003
Smith et al, AJRCCM 2004

eNO and Treatment Response

Adapted from Sikoff et al, Chest 2001
Identifying non-compliance

Detect loss of control

<table>
<thead>
<tr>
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<th>Positive predictive value (confidence interval)</th>
<th>Sensitivity (confidence interval)</th>
<th>Specificity (confidence interval)</th>
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<tbody>
<tr>
<td>NO at visit prior to loss of control = 15 ppb</td>
<td>0.13 (0.62, 0.94)</td>
<td>0.50 (0.37, 0.63)</td>
<td>0.65 (0.38, 0.88)</td>
</tr>
<tr>
<td>Change in NO from baseline visit prior to loss of control = 50%</td>
<td>0.13 (0.62, 0.94)</td>
<td>0.50 (0.32, 0.63)</td>
<td>0.65 (0.30, 0.88)</td>
</tr>
<tr>
<td>Percentage eosinophils at baseline = 4%</td>
<td>0.10 (0.51, 0.96)</td>
<td>0.21 (0.12, 0.34)</td>
<td>0.80 (0.52, 0.96)</td>
</tr>
<tr>
<td>SaeNO at baseline = 82.12 ml</td>
<td>0.11 (0.50, 0.98)</td>
<td>0.50 (0.32, 0.67)</td>
<td>0.50 (0.25, 0.75)</td>
</tr>
</tbody>
</table>


eNO Predicts Relapse in Pediatrics

• 40 children well controlled on ICS
• ICS stopped and children followed for 24 weeks
• 9 patients relapsed
  – >1 exacerbation/month
  □ β-agonist 4 days/week for at least 2 weeks
  – Peak flow variability >20%
• eNO higher at 2 and 4 weeks
  – Specific (93%) & sensitive (71%): eNO >48ppb at 4 wks

FOLLOWING THE GUIDELINES
NAEPP AND GOLD

- The guidelines focus on four components of care:
  1) measures to assess and monitor asthma
  2) patient education
  3) control of environmental factors and other conditions that can worsen asthma and
  4) medications

“Overall, these components have stood the test of time, and many of the earlier recommendations have been solidly confirmed by additional research throughout the years.” Our review of the recent scientific evidence helps us incorporate these four components even more effectively to provide quality asthma care.

MEASURES TO ASSESS AND MONITOR ASTHMA & COPD

- Complete pulmonary function lab
- NiOX monitor to evaluate FeNO levels: reflective of the inflammatory component of allergic asthma
- Impulse oscillometry: used to measure lung fx in children with a high degree of sensitivity and specificity to sm a/w impairment and asthma

WHY WE TEACH

A CONSISTENT APPROACH TO ASTHMA EDUCATION REDUCES HOSPITAL and EMERGENCY ROOM RE-ADMISSION RATES

- Resp Care Nov 2008 53(11):1542
- E. Conway
- S. Brungs
- L. Deveto
- D. Herzog
PATIENT EDUCATION

• EPR-3 confirms the importance of teaching patients skills to self-monitor and manage asthma and to use a written asthma action plan, which should include instructions for daily treatment and ways to recognize and handle worsening asthma.

DISPARITIES IN ASTHMA CARE

THE AAFA (Asthma and Allergy Foundation of America) RESEARCH REPORT

• Ethnic differences in asthma prevalence, morbidity and mortality are correlated with poverty, urban air quality, indoor allergens, inadequate medical care and lack of patient access and education

• In WI, lifetime asthma prevalence among adults increased from 10.6% in 2000 to 13.7% in 2009.
RESEARCH DATA (cont)

• Among WI adults, lifetime prevalence of asthma was twice as high in non-Hispanic African Americans as in non-Hispanic whites
• Children had the largest increase in prevalence and had greater health care use but adolescents had the highest mortality
• The asthma burden was borne disproportionately by Black children

Impact of Asthma in the United States

Asthma is a chronic inflammatory disease of both the large and small airways. It is expensive and there is no cure.1

Asthma costs the United States $56 billion each year.1 In 2010, 18.7 million adults (equal to 1 in 12 adults) and 7 million children (equal to 1 in 11 children) had asthma.1

In 2008, asthma caused:
• 10.5 million missed school days
• 14.2 million missed work days

Asthma Morbidity Now Versus a Decade Ago

Comparison of patients attended in 1998 (n = 1788) and 2009 (n = 2294)

- Patients exacerbations
- Emergency department visits
- Hospitalizations
- Any of these

Blue = 1998
Gold = 2009
n = 1788
n = 2294
undiagnosed asthma

• Major symptoms among the undiagnosed
  • Cough approx. 58%
  • SOB approx. 49%
  • Chest tightness approx. 38%
  • Wheezing approx. 32%
  • 2/3 did not report symptoms to a doctor
    • Time limited visits
    • Symptom recognition, tolerance and acclimation
  • Most have a diagnosis of recurrent bronchitis
  • Most don’t even have a current SABA
  • Few of those have been adequately evaluated
  • Strongly connected to ETS exposure-pre and postnatal

under-diagnosed asthma

Under-diagnosed asthma comprised about 1/3 of all identified asthma cases

1) Under-diagnosed means under-managed
2) Contributes to poor outcomes
3) Responsible for early a/w remodeling & increased risk of mortality and long term impairment
4) Associated with low physical activity
5) Also with increased BMI
6) Affects psychosocial development
7) Most don’t even have a current SABA
8) Few of those have been adequately evaluated

severity classification per patient

• Most asthma is self-assessed relying upon symptom recognition-frequency, intensity and duration
• Inverse relationship between the subjective assessment of asthma and the objective measurement
• ACT’s can be misleading
ASTHMA CONTROL TEST

Q1. 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?
   Most Frequent Response (MFR): #2 Most of the time

Q2. During the past 4 weeks, how often have you had shortness of breath?
   MFR: #1 More than once a day

Q3. During the past 4 weeks, how often did your asthma sx’s wake you up at night?
   MFR: #1 4 or more noc’s/wk

Q4. During the past 4 weeks, how often have you used your albuterol-MDI or neb?
   MFR: #1 3 or more times per day

Q5. How would you rate your asthma control during the past 4 weeks?
   MFR: #3 SOMEWHAT CONTROLLED

Asthma Is a Chronic Inflammatory Disease of Both the Large and Small Airways

Small Airway Resistance Accounts for At Least Half of Total Pulmonary Resistance in Asthma

50% to 90% of total pulmonary resistance
549% of total pulmonary resistance
Uncontrolled Asthma Is Associated With Small Airway Dysfunction

- FEF25%-75% (a measure of small airway function)
- FEV1 (a measure of large airway function)

Controlled Asthma (n = 57)

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<th>Asthma Status</th>
<th>FEF25%-75%</th>
<th>FEV1</th>
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<tr>
<td>Uncontrolled</td>
<td>4%</td>
<td>5%</td>
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Uncontrolled Asthma (n = 44)

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Most Underdiagnosed Populations

- African Americans
- Hispanics
- Children
- Elderly
- Low income residents

These are the largest producers of all the negative outcomes and highest medical resource utilizers

- Journal of Respiratory Care Science OCT 2011

AIM Survey: Majority of Patients Have “Not Well Controlled” or “Very Poorly Controlled” Asthma

- 71% of asthma patients in the AIM survey met NAEPP criteria for “Not Well Controlled” or “Very Poorly Controlled” asthma

Control Classification Based on NAEPP EPR-3 (N = 2500)

- Well Controlled: 29%
- Not Well Controlled: 24%
- Very Poorly Controlled: 47%

AIM = Asthma Insight and Management Survey

HELPING UNINSURED

• We Have No Support for uninsured patients.
• We charge a $50 co-pay and provide them with asthma controller medications
• This barely covers the cost of a visit
• Your referrals of insured patients helps us to help uninsured patients
• Patients are signed up for PAP or referred to a program specialist

Conclusion

• Asthma has reached epidemic proportions-CDC. Milwaukee is a top ten city for asthma
• Early and accurate assessment of respiratory function is essential in dx’ing, monitoring and treating respiratory conditions in these populations
• Education is vital to asthma/COPD management
• If your specialist is not providing this key component, your patient is being under-managed
• Early intervention produces the best outcomes

ASTHMA ACTION PLAN
Interpretation of IOS Results

- Except for central resistance, all IOS parameters showed increased abnormality with increased asthma severity and airflow obstruction.

Definition of Fractional Exhaled Nitric Oxide (FeNO)

- A noninvasive biomarker of airway inflammation studied in more than 2000 peer-reviewed articles.
- FeNO measurement:
  - Is performed by having a patient exhale a single breath into a nitric oxide analyzer.
  - Provides results similar to eosinophil count in induced sputum.
  - Offers a significantly higher diagnostic yield than spirometry.
  - Correlates well with eosinophilic inflammation and accurately reflects extent of inflammation.

- FeNO use is of high clinical value in assessing underlying inflammatory disease activity of asthma patients and in monitoring and managing their disease.
American Thoracic Society Clinical Practice Guideline on FeNO

Recommends use of FeNO to:
- Diagnose eosinophilic airway inflammation
- Determine the likelihood of corticosteroid responsiveness in patients with chronic respiratory tract symptoms possibly arising from airway inflammation
- Support the diagnosis of asthma in cases for which objective evidence is needed
- Monitor airway inflammation in patients with asthma

In April 2012, the ACAAI and AAAAI issued a joint position statement in support of the ATS guidelines on FeNO.

FeNO Is a Useful Measure in the Clinical Management of Asthma

- Fractional exhaled nitric oxide (FeNO) is a good surrogate marker of eosinophilic inflammation, which is associated with steroid responsiveness
- FeNO significantly correlates with bronchial hyperresponsiveness, bronchodilator reversibility, and atopy
- FeNO can help distinguish asthma from other respiratory conditions
- FeNO is reproducible and is associated with other markers of asthma severity
- FeNO is a useful measure for monitoring adherence to ICSs and for assisting in optimizing the dose of ICSs to obtain both symptom control and inflammation control
- Studies suggest that small-particle ICSs have a greater effect on alveolar FeNO than large-particle ICSs

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ACAAI, American College of Allergy, Asthma, and Immunology; AAAAI, American Academy of Allergy, Asthma, and Immunology.
Toward Control of Asthma

Control—the degree to which the manifestations of asthma (symptoms, functional impairment, and risk for untoward events) are minimized and goals of therapy are met

• Reduce impairment
  – Prevent chronic and troublesome symptoms
  – Require infrequent use (≤ 2 days/week) of short-acting β₂-agonist for quick relief of symptoms
  – Maintain (near) “normal” pulmonary function
  – Maintain normal activity levels
  – Meet patients’/families’ expectations and satisfaction with care

• Reduce risk
  – Prevent recurrent exacerbations and minimize need for ED visits/hospitalizations
  – Prevent progressive loss of lung function
  – Provide optimal pharmacotherapy with minimal/no adverse effects


Create Your Own Journey

• Every asthma patient’s journey (and yours!) will be different; however, common themes may exist
• Consider your patients’ perspectives and ways to break down barriers
  – Assess health literacy, worry, confusion, language/cultural issues, poor adherence, support system
• Explore options to motivate and improve self-management
• Is each patient taking medications properly and monitoring symptoms and use of reliever regularly and accurately?
• Consider your office environment: Is it user-friendly?
• The whole is greater than the sum of its parts: Consider group education and group appointments as options

George Bernard Shaw said:
“The single biggest problem with communication is the illusion that it has occurred.”
The problem of literacy
2003 National Assessment of Adult Literacy (NAAL)

• Estimated 43% of adults in the United States (about 93 million) had basic or below basic prose literacy skills
• Most adults with high school education or less and 13% of those with a college degree at lower literacy levels
• Average grade reading level of US adults estimated between 7th and 9th grade levels
• 20% of adults are estimated to read at the 5th grade level or below.
• Health information poses literacy requirements beyond general reading comprehension

The issue of health literacy

• Capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.
  – Includes reading, comprehension, speaking and numeracy (ability to use and understand numbers in daily life)
• People with lowest literacy had difficulty with:
  – Hypothetical scenarios of taking medicine at certain times during the day
  – Filling out patient information forms or correctly reading a health appointment slip
  – Understanding health information graphs
  – Calculating health insurance costs
• Health literacy skills generally lower among people with lower education, lower income, who are members of a minority group, or are 65 years of age or older.

Current health information

• Readability significantly exceeded estimated reading skills of target audiences
• More than 1,000 studies of health print materials, including medication labels and packaging, and web sites:
  – Health text readability at or above 10th grade reading level
  – College and graduate school levels are not unusual for patient health communications that describe risk and that are written or reviewed by lawyers and/or scientists.
Common current practice

• Decide directions, risks and benefits to communicate
• Write Med Guide ostensibly to be understood by patients
• Write communications ostensibly to be used by HCPs

Common current practice

• Write KAB survey questionnaires
• Test at 18 months
• Try to figure out why the messages did not get across

How does that work for you?
Improving the communication in instructions/ risk communication "helps!"

Common current practice

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How does that work for you?
Improving the communication in instructions/ risk communication "helps!"
A Primer on Health INSTRUCTIONS/RISK Communication

“If we have not gotten our message across, we ought to assume that the fault is not with our receivers.”

Baruch Fischhoff
Department of Engineering and Public Policy
Carnegie-Mellon University (1985)
Department of Health and Human Services
Agency for Toxic Substances and Disease Registry

First and foremost - Instructions/Risk communication is communication!

Improving risk communication
• Focus on key Instructions/messages(dose, amounts, technique)
• Simplify text and format
• Use Plain Language
• Involve end-user in design
• Test comprehension and usability before deploying (patients and HCPs)
  – Validate content and format to ensure meeting communication goals
What is Plain Language?

• Concise, simple, well-organized writing
• Effective communication with specific audience to maximize messaging
• Provides essential information
  – No unnecessary words or expressions
  – Avoids jargon, redundancy, ambiguity, and obscurity, unnecessary complexity
• Grammatically correct
• Easy or NO math

What Plain Language is not:

• Unprofessional writing
• Method of "dumbing down" or "talking down" to reader
• Over-simplified to point of inaccuracy
• Only for patients with low-literacy
• Only for patients

Improving usability of health information

• Identify intended users
• Engage end-user in design
• Limit number of messages
• Use Plain Language
• Focus on behaviors
• Supplement text with graphics
• Check for understanding

http://www.cdc.gov/healthmarketing/healthliteracy/training/page1348.html
THE Best Reference:

- Read the Guide: *Communicating Risks and Benefits: An Evidence-Based User’s Guide* [PDF - 3.128KB] Baruch Fischhoff, PhD, Noel T. Brewer, PhD, & Julie S. Downs, PhD, editors

US Department of Health and Human Services
Food and Drug Administration
Risk Communication Advisory Committee and consultants