Using Objective Measures of Lung Function to Assess Asthma and Improve Inhalation Technique

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Asthma Ready® Communities

Disclosure

• Dr. Francisco and Dr. Rood have no financial interest in any commercial entity discussed in this presentation
• Dr. Francisco and Dr. Rood will not discuss experimental or off-label use of medications or devices

1. Describe EPR3 standards for assessment of lung function, review asthma tools which measure airflow, and use a digital flow meter to assess FEV1 and peak flow.

2. Use the FEV1-based “target time” approach and an In-Check Dial® to individualize inhaler training, document status before and after coaching and bill inhalation instruction (94664).

3. Identify EPR3 standards, common errors and critical aspects of inhalation instructions.
Objective #1

Describe EPR3 standards for assessment of lung function, review asthma tools which measure airflow, and use a digital flow meter to assess FEV1 and peak flow.

Seven Critical Strategies

(Adapted from "Partners Putting Guidelines into Action", 2008)

1) Prescribe inhaled corticosteroids
2) Provide a written asthma action plan
3) Assess severity, then monitor control
4) Schedule periodic visits & education
5) Use objective measures of airflow
6) Assess/improve inhalation technique
7) Bill for necessary services

Asthma Care Quick Reference (EPR3)

http://www.nhlbi.nih.gov/guidelines/asthma/asthma_qrg.pdf
Assessment Components

• Severity (Impairment & Risk)
• Control (Impairment & Risk)
• Responsiveness
  • “The ease with which asthma control is achieved by therapy.”
  • Exacerbations – reversibility of airflow obstruction and symptoms to
treatments at home (p. 382) & clinic/ED (p. 380)

Component Criteria

<table>
<thead>
<tr>
<th>Impairment</th>
<th>Risk</th>
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<tbody>
<tr>
<td>Days/week of asthma symptoms</td>
<td>Oral systemic steroid burst- OSB</td>
</tr>
<tr>
<td>Asthma-related nighttime awakenings</td>
<td>Medication side-effects</td>
</tr>
<tr>
<td>Days/week of SABA use</td>
<td></td>
</tr>
<tr>
<td>(not for SABA used to prevent EIB)</td>
<td></td>
</tr>
<tr>
<td>Interference with normal activity</td>
<td></td>
</tr>
<tr>
<td>Lung function FEV1, FEV1/FVC-preferred</td>
<td></td>
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</tbody>
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Severity –
Initiating
Therapy
(p. 5)
Use Objective Measures of Airflow

Spirometric parameters improve assessment of severity, control exacerbations and response to therapy (FEV1, FEV1/FVC ratio and PEF). Symptom reports are also useful, but under-estimate the degree of airway obstruction in many individuals.

(p. 43-45)

Classification of Asthma Severity in Children

The Contribution of Pulmonary Function Testing

Conclusions: In 2 different studies of inner-city children with asthma, approximately one third of the participants were reclassified into higher National Asthma Education and Prevention Program asthma severity categories when pulmonary function was considered in addition to symptom frequency. This may have direct implications for the undertreatment of asthma.

Arch Pediatr Adolesc Med. 2006;160:844-850
**Spirometry Components**

- **Forced Vital Capacity (FVC)**
  - The maximal volume of air forcibly exhaled from the point of maximal inhalation

- **Forced Expiratory Volume in 1 second (FEV1)**
  - The volume of air exhaled during the first second of the FVC

- **Ratio of FEV1 to FVC (FEV1/FVC)**
  - Expressed as a percentage

- **Peak Expiratory Flow (PEF)** — useful for gauging severity of exacerbations
  - Maximum air flow rate during forced exhalation

- The predicted values depend on the individual’s age, gender, height, and race
Is airflow obstruction present and is it at least partially reversible?

Use spirometry to establish airflow obstruction
- FEV₁ < 80% predicted
- FEV₁/FVC below the lower limit of normal, as compared to the individual's own predicted value

Use spirometry to establish reversibility
- FEV₁ increases > 12% in patients ≥ 12 yo and > 15% in patients < 12 yo
- > 200 ml after using a short-acting inhaled beta₂ agonist
- 2- to 3-week trial of oral corticosteroid therapy may be required

Reliability of Spirometry

- Patient
  - ATS ≥ 5 yo
  - Effort dependent

- Professional
  - Trained staff
  - Correct technique, calibration, and maintenance

Reliability of Spirometry cont’d...

Criteria for acceptability include:
- Lack of artifact induced by coughing, glottic closure, or equipment problems (primarily leak);
- Satisfactory start to the test without hesitation or early termination; and
- Satisfactory exhalation with 6 seconds (for ≥ 9 yo; 3 seconds for < 9 yo) of smooth continuous exhalation or a reasonable duration of exhalation with a plateau.
Repeatability Criteria: ATS/ERS Guidelines

- 3 acceptable tests
- 2 best tests having FEV1 and FVC within 150 mL of each other
- Can have 8 attempts to produce acceptable, repeatable tests

Objective Measures of Lung Function

- Full Spirometry every 1-2 years
- “Spirometry light” FEV1 at every visit
- How’s my lung number today?
- Is my ICS working?
Exacerbation – Treatment Response

<table>
<thead>
<tr>
<th>Good response</th>
<th>Incomplete response</th>
<th>Poor response</th>
</tr>
</thead>
</table>

FEV1 is the vital sign of asthma!!!(Life-threatening)

Pop Quiz (matching)

1) Usually normal with asthma  
2) Best exacerbation parameter  
3) Best for assessing control  
4) Best for home monitoring

- a) FEV1, b) FVC, c) FEV1/FVC, d) PEF

Multimedia – "Spirometry Fundamentals"

Assessment Criteria (airflow)

- Clinic
  - Severity: FEV1/FVC, FEV1
  - Control: FEV1/FVC, FEV1
  - Exacerbations: FEV1*, PEF
- Home, control/exacerbations, PEF (or FEV1*)
  - preferred (more sensitive)
Digital Flow Meter – FEV1 & PEF

- Asma-1
- Exacerbations
- Peak flow zone determination
- $50, multi-use $0.35/patient

Predicted FEV1 – by gender, age, height and race

FEV1/Peak Flow Calculator

Name:  
Age: 7  
Ht (cm): 125  
Gender: Male  
Race: Caucasian  

Peak Flow
FEV1: 185
1.39

100% 80%

Manual Data Entry
Calculated Value
Value of the Ratio

- 16 yr Caucasian male sees specialist
- Height 185 cm; weight 100.1 kg
- History obtained- no complaints, no impairment taking once daily Asmanex
- Spirometry: FEV1 95%; FEV1/FVC=68
- This is obstruction, he is at risk (hobby extreme outback camping)

Percent Predicted FEV1

- 10 yr old Caucasian female; 146 cm
- Personal best FEV1 = 2.63
- Today's FEV1= 2.0
- Today's FEV1/baseline FEV1 (2.0 ÷ 2.63 = 0.76 x 100 = 76% of personal best
- Percent predicted FEV1 was only 2.2. Use of a reference chart WOULD NOT have accurately assessed his airflow obstruction
- (2.0/2.2=0.90x100=90% of predicted)
Digital Lung Monitor (COPD-6)

- FEV1, FEV6 & ratio
- Assess control
- Age, height, race & gender
- $100, multi-use $0.38/patient

Equipment Info

Home Peak Flow Meters

- Home monitoring
- Poor perceivers
- Hx of severe attacks
- $25 (Internet price)
- Diurnal variability
- When Sx are present or Rx changing
Objective #2

Use the FEV1-based "target time" approach and an In-Check Dial® to individualize inhaler training, document status before and after coaching and bill inhalation instruction (94664).

What is a target time?

• Using knowledge of FEV1 to guide self-regulation of inspiratory flow
• Gently and completely exhale (~FEV1)
• Lift chin and refill lungs in a calculated amount of time
• Time of refilling is a proxy for inspiratory flow rate

Old air out – aim up – fill up in your target time!

EPR3 Specifies IFR and IFT

• IFR= inspiratory flow rate
• IFT= inspiratory flow time

• MDI – 30 LPM or 3-5 seconds (p. 250)
• DPI – 60 LPM or 2-3 seconds (p. 249)

How do you measure IFR & IFT?
**FEV1 Estimates IFT at EPR3 IFR**

- MDI: @30 LPM, it takes 2 sec. to get a liter of air into the lungs.
  If FEV1=2.5L @30 LPM, IFT=5 sec.
- DPI: @60 LPM, it takes 1 sec. to get a liter of air into the lungs at this rate, if FEV1=2.5L @60 LPM, IFT=2.5 sec.

This is the “target time” approach to teaching inhalation technique.

**In-Check Dial™ G-16 Device**

- Set resistance for inhaler type
- Use disposable one-way filter
- Train for optimal IFR and IFT
- MDI IFT=2xFEV1

**Estimating Target Time**

MDI = FEV1 x 2 sec, DPI = FEV1 x 1 sec
Inhalation Worksheet

Take Time to Check Inhalation

• Asthma therapy hinges on inhalation
• Your patients/families know if they have not been adequately trained
• You can bill for this important service – 94664 (Every insurer in MO reimburses)
• See "Inhalation Instructions Guide"

Provide and Bill Inhalation Instructions – CPT code 94664
Implementing Asthma Best Practices

Adaptation – VHC w/Mask

- “Inhalation Instruction Guidelines…”
- Page 2,
- Second bullet – teach device tolerance with no medication first, then use “Count and Cheer” method
- Third bullet – Intentional emptying, slow filling and breath-holding

Objective #3

Identify EPR3 standards, common errors and critical aspects of inhalation instructions.
Disclaimer

• You should always consult FDA or manufacturers’ product information (PI). 
  Postmarket Drug Safety Information for Patients & Providers. The following slides aim to review common features of inhaled medication devices. Examples will be provided to illustrate the need to be attentive to unique product features that impact asthma care.

FDA Website for Drug Information

“Postmarket Drug Safety Information for Patients & Providers”

OR

“Index to Drug-Specific Information”

Index to Drug-Specific Information

Note: This index does not include all FDA approved drugs. It only includes drugs that have been the subject of a Drug Safety Communication, Health Update, Professional Information alert, Early Communication About an Ongoing Safety Review, or other important information. Please use Drugs@FDA to access the information of a drug not found in the index.

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Why Focus On Inhalation Technique?

Valved-holding Chamber for ALL MDI Medications!!

Do People With Asthma Know How To Effectively Inhale Medications?
Resistance of 3 Common Inhalers at different flow rates (placebo versions)

- AstraZeneca's Turbohaler
- GlaxoSmithKline's Diskus
- 3M's HFA pMDI

Imagine the effect when drinking through a straw......

- Low Resistance
- Medium Resistance
- High Resistance
Does inspiratory resistance really matter that much? Boehringer-Ingelheim seemed to think so when they reformulated tiotropium from a high resistance DPI to a low resistance SMI (soft mist inhaler)

Inspiratory Flow Influences Drug Deposition

<table>
<thead>
<tr>
<th>Inspiratory Flow</th>
<th>Drug Deposition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Too Slow</td>
<td>Throat</td>
</tr>
<tr>
<td>Too Fast</td>
<td>Throat</td>
</tr>
<tr>
<td>Correct Speed</td>
<td>Lungs</td>
</tr>
</tbody>
</table>

Common MDI Inhalation Errors

- Failure to exhale fully prior to dose resulting in inadequate volume of inhaled air with lower net dose
- Inhalation too rapid, leading to impaction of drug against pharynx and bifurcations of the airway
• All HFA inhaler inhalers should be shaken immediately prior to each actuation (puff dispensed).

True or False?
HFA MDI – Education

• Position your thumb below the inhaler in opposition to your fingers on top of the canister
• Aim inhaler into the back of the throat (not towards the cheeks, tongue or roof of your mouth)
• Take a slow, deep breath as you press down firmly on top of the canister

HFA MDI – Education

• Continue to breathe in, slowly filling your lungs with air and medication
• Hold your breath for 10 seconds or as long as you comfortably can
• Before breathing out release the canister and remove the inhaler from your mouth, keeping inhaler upright

HFA MDI – Education

• Wait one minute
• Then shake inhaler (not Alvesco, Brunov or QVAR) again for 5 seconds and repeat the steps above
• When last inhalation is complete replace the mouthpiece cover
• Store at room temperature, avoid temperature extremes
HFA MDI – Education

- If your HFA is an inhaled corticosteroid remember to rinse your mouth with water and spit this water into a sink
- Observe the maximum number of inhalations associated with some products (Advair & Symbicort - 2/24)
- If no counter, record number of inhalations taken, replace at dose limit
- Store upright, mouthpiece down (in box?)

HFA MDI – Education

- Open mouth technique is not recommended for any HFA product
- An HFA plume disperses laterally and is not easily directed into the mouth by open-mouth technique as was a CFC medication

MDI Inhalation Technique

- Tilt head back slightly
- Exhale fully
- Inhale medication at 80 LPM for at least 3 seconds (use 2x FEV1 target)
- Hold breath for 10 seconds if able
- Exhale, rest, then repeat if additional doses are indicated at 1 minute intervals
Valved Holding Chambers vs. Spacers

Valved Holding Chambers
- VHC has one way valve
- Less time-sensitive
- Decrease particle velocity
- Reduce pharyngeal deposition
- Can be used by infants and children with a mask

Spacers
- Extension device
- No valve
- Time sensitive
- Decrease particle velocity
- Reduce pharyngeal deposition

Valved-Holding Chambers
- Reduce oral deposition and likely lower risk of oral candidiasis with ICS use
- Probably increase lung deposition, evidence lacking for specific HFA formulations
- Recommended by EPR3 1) for “individuals who have difficulty performing adequate MDI technique”, p. 250... [MOST PEOPLE]
  2) For managing asthma exacerbations, p. 386 & 387 (with face mask if <6),
  Could be anyone!!!

VHC Models Comparison
- One-way valve?
- Excessive flow indicator?
- Static-free?
- Mask available?
- Efficacy data available?
- Cost comparison to similar models?

"With Mouthpiece Only"
DPI Inhalation Technique

- Tilt head back slightly
- Exhale fully
- Inhale medication at 60 LPM for at least 2 seconds (use FEV1 in seconds)
- Hold breath for 10 seconds if able
- Exhale, rest, then repeat if additional doses are indicated

Diskus® Features

- Multi-dose DPI
- Lactose carrier
- Inspir. flow rates 30–90 l/min
- 60 doses per container
- ICS
  - Fluticasone (Flovent)
- Combination
  - Fluticasone/salmeterol (Advair)
- LABA
  - Salmeterol (Serevent)

Diskus® Teaching Points

- Do not shake
- Do not exhale into the device
- Never wash mouthpiece or any part of Diskus. Wipe mouthpiece with dry tissue after use
- Always recap after use
- Rinse mouth after use
- Store in a dry place
- Discard six weeks after removal from foil pouch or when counter reads “0”, which ever comes first
- Internal counter. The last five doses are displayed in red. When numbers appear in red, obtain refill
The ELLIPTA® Dry Powder Inhaler: Design, Functionality, In Vitro Dosing Performance and Critical Task Compliance by Patients and Caregivers

Andrew C. Grant, BSc,1,* Richard Walker, BSc,2 and Karl Garrill, BSc3

"It has moderate resistance to airflow and can hold one or two blister strips, with each blister containing a sealed single dose of medication."


Ellipta – “open, inhale, close”

Ellipta® inhalers
Ellipta – Don’t block air vent

Ellipta® inhalers
• Arnuity®- fluticasone furoate (ICS)
  • 100 or 200 mcg; asthma, COPD
• Breo®- fluticasone furoate & vilanterol; ICS + LABA)
  • 100/25 or 200/25; asthma, COPD
COPD only
• Incruse®- umeclidinium (anticholinergic)
• Anoro®- umeclidinium and vilanterol (anticholinergic & LABA)

Pressair
**Turdoza™ Pressair™**

**aclidinium bromide inhalation powder**

- Long acting anticholinergic for COPD
- Dose – 400 mcg 1 inhalation twice daily
- Preloaded in a sealed labeled aluminum pouch 60 or 30 doses
- Breath activated
- Dose counter
- Do not use if severe proteins (contains lactose)

---

**“Press, release, inhale”**

- Hold Pressair™ with green button facing up
- PRESS and RELEASE

---

**Inhale...**

- Blow out- Do not blow into device
- INHALE rapidly and deeply- listen for “click”
**Arccpta™ Neohaler™**

Indacaterol inhalation powder

- Long acting beta-agonist for COPD
- Dose – 75 mcg one inhalation once daily; do not use more than once every 24 hrs
- Capsules of dry powder – Do not swallow!
- Blister card

**Neohaler™ Assembly**

- Take one blister from card
- Push capsule through foil, take off cover and open Neohaler™
- Place capsule in device, close inhaler, listen for “click”

**How to inhale Neohaler™**

- With mouthpiece up, firmly press buttons on the sides of the inhaler to pierce capsule.
- Empty lungs, do not blow into inhaler
- Seal lips around mouthpiece, hold inhaler with buttons left to right
- Inhale rapidly and deeply to hear capsule vibrate, hold breath
- Check capsule, if powder visible, repeat steps
Arca Neohaler Positioning

Asmanex® Twisthaler®

Flexhaler® Features

• Multidose DPI
• Lactose carrier
• Inspiratory flow rates of ~ 60 - 90 l/min
• 90 mcg: 60 doses per container
• 180 mcg: 120 doses per container
• ICS
  • Budesonide (Pulmicort)
Flexhaler® Teaching Points

- “Prime” before first use, dose loading
- Do not shake
- Do not exhale into the device
- Clean mouthpiece after use with tissue
- Always recap after use
- Rinse mouth after use
- Store in a dry place with cover on
- Internal counter – read middle of window
- Discard when counter reads “0” on red background. When you see the red background, obtain refill

Nebulizers

Jet
- Air driven
- Longer treatment times
- Less cough and irritation than ultrasonic nebulizer

Ultrasonic
- High frequency sound waves
- Heat can alter drug
- Shorter treatment times
- Larger droplet size

Nebulizers

Advantages
- Many breaths used to inhale Rx (less missed)
- Can aerosolize large amounts of diluent
- Can nebulize multiple meds
- Can use with oxygen
- Humidifies airways
- No propellant

Disadvantages
- Only fraction deposited
- Need higher doses
- Longer treatment times
- Bulky, needs electricity
- More expensive?
- Risk of contamination
- Many use blow-by, little actual lung deposition
Nebulizers Medications by Class

**Single**
- ICS - budesonide
- SABA - albuterol sulfate
- SABA - levalbuterol hydrochloride
- Anticholinergic - ipratropium bromide
- LABA - aformoterol tartrate (Brovana®)
- LABA - formoterol fumarate (Performist®)

**Combination**
- SABA/Anticholinergic - albuterol sulfate/ipratropium bromide

Common DPI Inhalation Errors

- Failure to exhale fully prior to dose resulting in inadequate volume of inhaled air with lower net dose
- Inhalation too slow, leading to sedimentation of drug in the mouth and pharynx (weight of drug favors falling from the airstream and settling on the oropharyngeal)

Give Parents Options for Delivering ICS
When Training Is Difficult

- Some individuals will be unable to remember their inhalation technique.
- So before each ICS dose practice taking a breath with a “coach” watching before actually breathing in the medicine.
- When your practice breath is good (you exhaled fully, positioned your airway and filled-up in your target time) you’re ready.

Trainhaler with Flo-Tone

Aerochamber with Flow-Vu

http://www.aerochambervhc.com/overview
Application: Case In Point

Which of the following regimens is probably best for a 14-year-old with severe asthma?

1) Breo® Ellipta® 200/25 1 inhalation daily and Proventil® 2 puffs Q4 hr prn
2) Dulera® 200/5 2 puffs BID and Ventolin® 2 puffs Q6 prn
3) Advair® HFA 230/21 2 puffs BID and ProAir RespiClick 2 inhalations Q4 pm

Asthma Training Opportunities

How Do We Implement Best Practices?

- Learning together (ECHO®)
- Academic Detailing (supplies, routines)
- Performance feedback (claims data)
- Practice facilitation (seeing patients)

Implementing Asthma Guidelines Using Practice Facilitation and Local Learning Collaboratives: A Randomized Controlled Trial

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4018371/
Project ECHO® (Extension for Community Healthcare Outcomes) helps democratize medical knowledge and develops specialty care capacity in underserved communities.

Using a revolutionary model of telementoring, collaborative medical education and care management, Project ECHO empowers front-line primary care professionals to provide the right care, in the right place, at the right time.

THE TRANSFORMATIVE MODEL IN MEDICAL EDUCATION AND CARE DELIVERY

https://www.youtube.com/watch?v=VAMaHP-tEwk


MO ECHO® Key Purposes

- “Safely & effectively treat common & complex conditions in rural & underserved areas”
- “Decrease treatment delays and the need for patients to travel to see specialists”
- “Utilize community health care workers to address social determinants, improve adherence and health outcomes”

Extension for Community Health Outcomes - Asthma
https://showmeecho.org/clinics/asthma/

Thank you!