A *Breath* of Fresh Air?
An update of novel inhalers used for the treatment of asthma and COPD

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RIPF Kimberly McDonough Spring Seminar

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Disclosure

- I have no actual or potential conflicts of interest associated with this presentation or products mentioned within

Objectives

Pharmacists

- Review indications and dosing for new inhalers in the treatment of asthma/COPD based on current primary literature
- Identify patient specific factors which contribute to non-adherence with current inhaler devices
- Design a therapeutic treatment regimen for patients at high-risk of non-adherence
- Demonstrate proper use of inhaler devices and counseling techniques

Technicians

- Identify patient specific factors which contribute to non-adherence with current inhaler devices
- Review common side effects associated with various inhalers

Evolution of Inhalers

Table 4. Some FDA-Approved Drugs for COPD

Drug	Some Formulations	Delivery Device	Usual Adult Dosage	Cost[1]
Inhaled Short-Acting Anticholinergic				
Ipratropium				
Atrovent HFA (Boehringer Ingelheim)	17 mcg/inhalation	HFA MDI (200 inh/unit)	2 inhalations qid PRN	$215.00[2]
generic – single-dose vials	200 mcg/mL soln	Nebulizer	500 mcg qid PRN	18.00[2]
Inhaled Short-Acting Beta$_2$-Agonist/Short-Acting Anticholinergic Combination				
Albuterol/ipratropium				
Combivent[3] (Boehringer Ingelheim)	90 mcg/18 mcg/ inhalation	CFC MDI (200 inh/unit)	2 inhalations qid PRN	216.00[2]
Combivent Respimat (Boehringer Ingelheim)	100 mcg/20 mcg/ inhalation	MDI (120 inh/unit)	1 inhalation qid PRN	240.00[4]
DuoNeb (Dey)	2.5 mg/0.5 mg /3 mL soln	Nebulizer	2.5 mg/0.5 mg qid PRN	270.00[4]
generic				91.00[4]
Inhaled Long-Acting Beta$_2$-Agonists				
Indacaterol – *Arcapta Neohaler* (Novartis)	75 mcg/capsule	DPI (30 inh/unit)	75 mcg once/day	173.00
Salmeterol – *Serevent Diskus* (GSK)	50 mcg/blister	DPI (60 inh/unit)	50 mcg bid	190.00
Formoterol – *Foradil Aerolizer* (Merck)	12 mcg/capsule	DPI (60 inh/unit)	12 mcg bid	183.00
Perforomist (Dey)	20 mcg/2 mL soln	Nebulizer	20 mcg bid	472.00
Arformoterol – *Brovana* (Sunovion)	15 mcg/2 mL soln	Nebulizer	15 mcg bid	457.00
Inhaled Long-Acting Anticholinergics				
Tiotropium – *Spiriva HandiHaler* (Boehringer Ingelheim)	18 mcg/capsule	DPI (30, 90 inh/unit)	18 mcg once/day	260.00
Aclidinium – *Tudorza Pressair* (Forest)	400 mcg/inhalation	DPI (60 inh/unit)	400 mcg bid	218.00
Inhaled Corticosteroid/Long-Acting Beta$_2$-Agonist Combinations				
Fluticasone propionate/salmeterol – *Advair Diskus*[5] (GSK)	100, 250, 500 mcg/ 50 mcg/blister	DPI (60 inh/unit)	250/50 mcg bid	268.00
Fluticasone furoate/vilanterol – *Breo Ellipta* (GSK)	100 mcg/25 mcg/ blister	DPI (30 inh/unit)	100/25 mcg once/day	N.A.
Budesonide/formoterol – *Symbicort*[6] (Astra Zeneca)	80, 160 mcg/ 4.5 mcg/inhalation	MDI (120 inh/unit)	320/9 mcg bid	236.00
Phosphodiesterase-4 Inhibitor				
Roflumilast – *Daliresp* (Forest)	500 mcg oral tablet	none	500 mcg once/day	199.00

HFA = hydrofluoroalkane; MDI = metered-dose inhaler; CFC = chlorofluorocarbon; DPI = dry powder inhaler; inh = inhalation; N.A. = not available

1. Approximate wholesale acquisition cost (WAC) for 30 days' treatment at the lowest recommended adult dosage. $ource® Monthly (Selected from FDB MedKnowledge™) July 5, 2013. Reprinted with permission by FDB, Inc. All rights reserved. ©2013. www.fdbhealth.com/policies/drug-pricing-policy. Actual retail prices may be higher.
2. Cost for 100 doses.
3. The manufacturer is discontinuing *Combivent* in July 2013.
4. Cost for 120 doses.
5. Only the 250/50 mcg dose is FDA-approved for use in COPD.
6. Only the 160/4.5 mcg dose is FDA-approved for use in COPD.

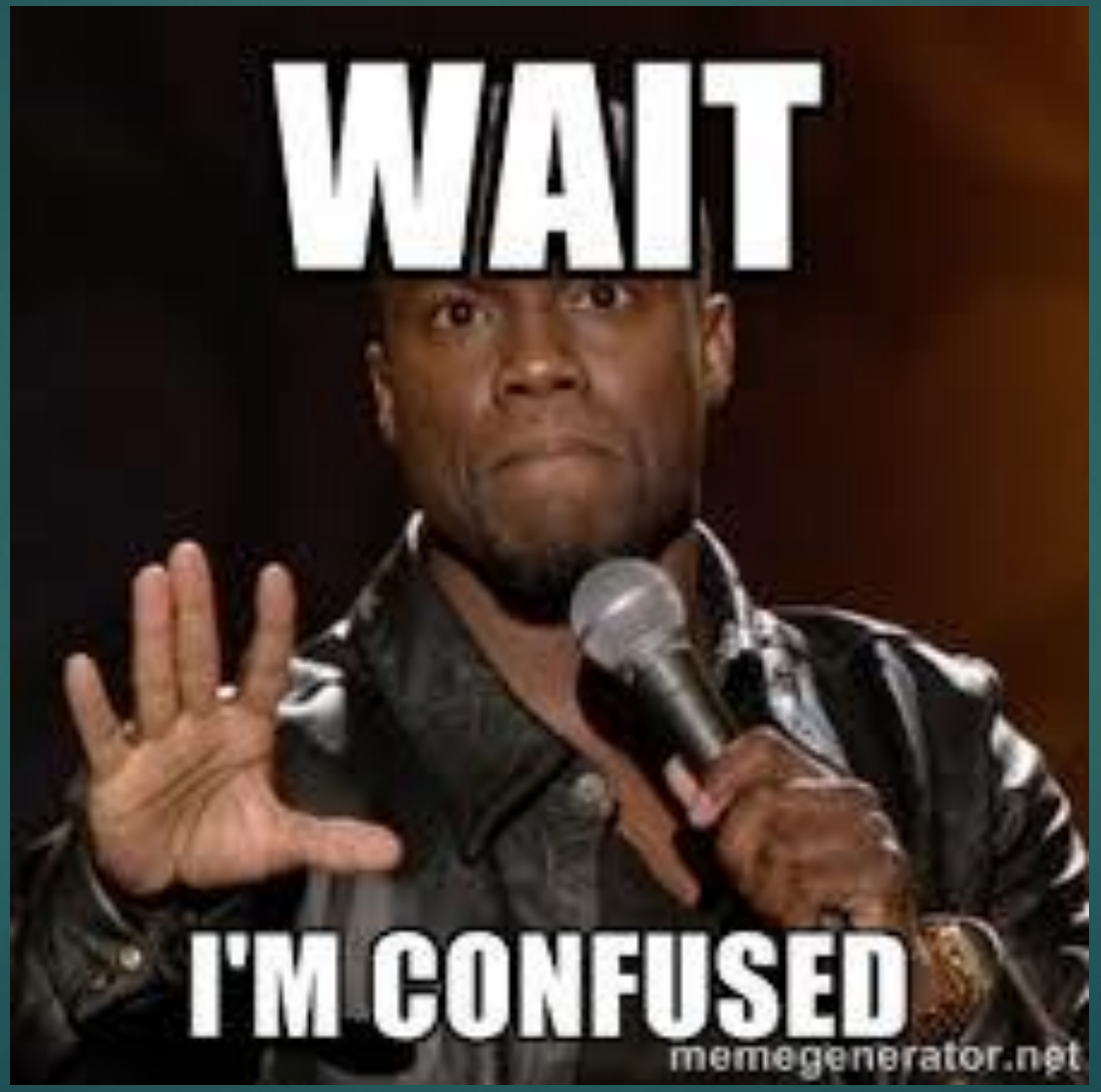
Table 2. Some FDA-Approved Drugs for Asthma

Drug	Some Available Formulations	Adult Dosage	Pediatric Dosage	Cost[1]
Inhaled Beta$_2$-Agonists, Short-Acting				
Albuterol –				
ProAir HFA (Teva)	HFA MDI (60[2] or 200 inh/unit)	90-180 mcg q4-6h PRN	≥4 yrs: 90-180 mcg q4-6h PRN	$45.00
Proventil HFA (Merck)	90 mcg/inhalation			52.00
Ventolin HFA (GSK)				40.00
generic	Solution for nebulization[3]	1.25-5 mg q4-8h PRN	2-4 yrs: 0.63-2.5 mg q4-6h PRN	
single-dose vials	0.63, 1.25, 2.5mg/3mL			24.00[4]
multi-dose vials	100 mg/20 mL		5-11 yrs: 1.25-5 mg q4-8h PRN	6.00[4]
AccuNeb (Dey) single-dose vials	Solution for nebulization[3] 0.63, 1.25 mg/3 mL	——	2-12 yrs: 0.63 or 1.25 mg tid-qid PRN	180.00[4]
Levalbuterol –				
Xopenex HFA (Sunovion)	HFA MDI (80, 200 inh/unit) 45 mcg/inhalation	90 mcg q4-6h PRN	≥4 yrs: 90 mcg q4-6h PRN	48.00
Xopenex (Sunovion)	Solution for nebulization[3]	0.63-1.25 mg tid q6-8h PRN	6-11 yrs: 0.31-0.63 mg tid q6-8h PRN	621.00
generic	0.31, 0.63, 1.25 mg/3 mL		≥12 yrs: 0.63- 1.25 mg tid q6-8h PRN	536.00
Pirbuterol[5] – *Maxair Autohaler* (Valeant)	Breath-actuated CFC MDI (80, 400 inh/unit) 200 mcg/inh	200-400 mcg q4-6h PRN	≥12 yrs: 200-400 mcg q4-6h PRN	409.00
Inhaled Corticosteroids				
Beclomethasone dipropionate – *QVAR* (Teva)	HFA MDI (100 or 120 inh/unit) 40, 80 mcg/inhalation	40-320 mcg bid[6]	5-11 yrs: 40-80 mcg bid[6]	120.00
Budesonide – *Pulmicort Flexhaler* (AstraZeneca)	DPI (60, 120 inh/unit) 90, 180 mcg/inhalation	180-720 mcg bid	6-17 yrs: 180-360 mcg bid	161.00
Pulmicort Respules (AstraZeneca) single-dose ampules	Suspension for nebulization[7] 0.25, 0.5 mg, 1 mg/2mL	——	1-8 yrs: 0.25 mg bid or 0.5 mg once/day or bid	308.00[8]
generic – single-dose vials	0.25, 0.5 mg/2mL		or 1 mg once/day[6]	220.00[8]
Ciclesonide – *Alvesco* (Sunovion)	HFA MDI (60 inh/unit) 80, 160 mcg/inhalation	80-320 mcg bid[6]	≥12 yrs: 80-320 mcg bid[6]	174.00
Flunisolide – *Aerospan* HFA (Acton)	HFA MDI (60, 120 inh/unit) 80 mcg/inhalation	160-320 mcg bid[6]	6-11 yrs: 80-160 mcg bid[6]	N.A.
Fluticasone propionate –				
Flovent Diskus (GSK)	DPI (60 inh/unit) 50, 100, 250 mcg/blister	100-1000 mcg bid[6]	4-11 yrs: 50-100 mcg bid[6]	121.00
Flovent HFA (GSK)	HFA MDI (120 inh/unit) 44, 110, 220 mcg/inhalation	88-880 mcg bid[6]	4-11 yrs: 88 mcg bid	121.00
Mometasone furoate – *Asmanex Twisthaler* (Merck)	DPI (30, 60, 120 inh/unit) 110, 220 mcg/inhalation	220-880 mcg once/day in evening or 220 mcg bid	4-11 yrs: 110 mcg 1x/d in evening	142.00

CFC = Chlorofluorocarbon; DPI = Dry powder inhaler; HFA = Hydrofluoroalkane; MDI = Metered-dose inhaler; inh = inhalation; N.A. = Not yet available

1. Approximate wholesale acquisition cost (WAC) for 30 days' treatment at the lowest recommended adult dosage. For SABAs, cost is for 100 doses. $ource® Monthly (Selected from FDB MedKnowledge™) July 5, 2013. Reprinted with permission by FDB, Inc. All rights reserved. ©2013. www.fdbhealth.com/policies/drug-pricing-policy. Actual retail prices may be higher.
2. Only *Ventolin HFA* is available as 60 inhalations/unit.
3. Nebulized solutions may be used for very young, very old and other patients unable to use pressurized aerosols. More time is required to administer the drug and the device may not be portable.
4. Cost of 100 2.5-mg doses (generics) or 1.25-mg doses *(AccuNeb)*.
5. CFC-containing MDIs will not be marketed after December 2013.
6. Dose is based on prior asthma therapy. See package insert for specific dosing instructions.
7. Only approved for use in children 1-8 years old.
8. Cost based on the lowest recommended pediatric dosage.

Right now you may be thinking…



Or…

Or maybe…

Happy Cinco de Mayo!

Let’s clarify these new devices!

New Inhalers Approved

- Since July 2012, the FDA has approved 11 new inhalers/ or devices!
  - 4 Ellipta
  - 4 Respimats
  - 1 Respiclick
  - 1 HFA
  - 1 Pressair

2012
2013

- Turdoza® Pressiar® (7/23/12)
- Anoro™ Ellipta® (12/18/13)

2014

- Asmanex® HFA (4/25/14)
- Striverdi® Respimat (7/31/14)
- Arnuity™ Ellipta® (8/20/14)
- Incruse™ Ellipta® (8/30/14)
- Spiriva® Respimat 2.5 mcg COPD (9/25/14)

2015

- Proair® Respiclick (4/1/15)
- Breo®Ellipta® (4/30/15)
- Stiolto® Respimat (5/26/15)
- Spiriva® Respimat 1.25 mcg Asthma (9/15/15

Inhalers by device/delivery system

Dry Powder (DPI)

Ellipta
-Anoro
-Arnuity
-Breo
-Incruse

Pressair
-Turdoza

Respiclick
-Proair

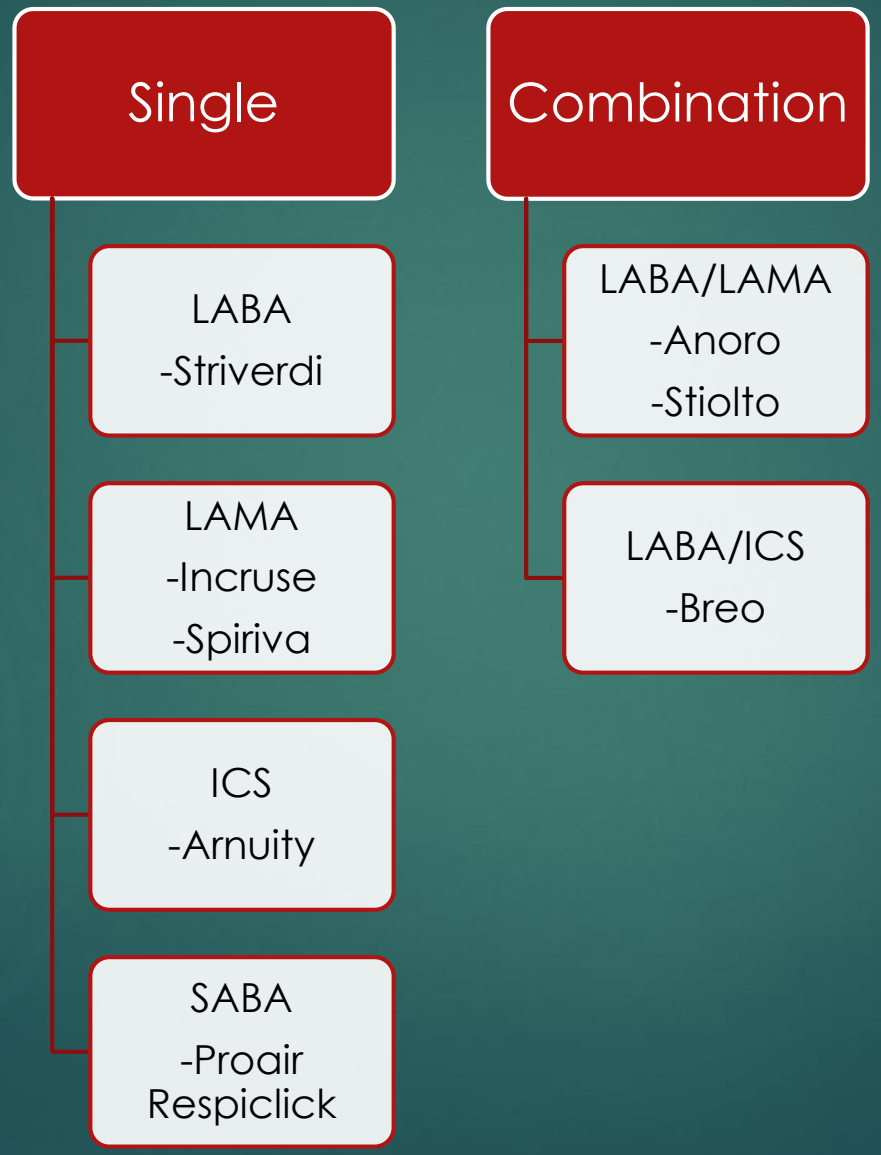
HFA

-Asmanex

Respimat

-Spiriva
-Stiolto
-Striverdi

Inhalers by Medication Class



Hands on activity!!

PLEASE MAKE GROUPS OF 4 AS WE WILL REVIEW THE NEW DEVICES!!

Ellipta Devices

- Anoro
- Arnuity
- Breo
- Incruse

Ellipta Devices

- Storage:
  - Must be thrown out once the dose reader reaches zero (at this point, no medicine is left) or 6 weeks after removing from foil pouch, whichever comes first
- Maintenance
  - Wipe mouthpiece with dry cloth or cotton swab as needed
  - Do not try to disassemble inhaler or immerse in water
- Precautions
  - Patients with severe milk-protein allergies should not use these devices as they may cause severe hypersensitivity reactions

Ellipta Devices

- Administation
  - Open the inhaler cover by pushing mouthpiece back.
  - Once you hear a click, the mouthpiece is fully exposed.
  - Take a deep breath in and breathe out fully and completely, away from the inhaler.
  - Place the inhaler to your lips and form a tight seal around the mouthpiece. Take a deep, quick breath in.
  - Make sure you do not block the air vent with your fingers.
  - Hold your breath for up to 10 seconds, or however long is comfortable.
  - Remove the inhaler from your mouth and breathe out.
  - Close the inhaler by placing the mouthpiece cover back over the mouthpiece.
- Dose counter
  - The Ellipta has a dose counter to indicate the number of doses left. When the dose counter turns red, it means you have limited medicine left (< 10 doses) and you need a refill.

Anoro
(umeclidinium/vilanterol)

- **Umeclidinium/vilanterol (LAMA + LABA)** combination is indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with COPD, available for delivery via the Ellipta® device.
- Dosing
  - 62.5 mcg/25 mcg – 1 puff inhaled by mouth ONCE daily

Anoro (umeclidinium/vilanterol)

- Clinical trials involving umeclidinium/vilanterol were able to demonstrate significant improvement in pulmonary function and symptom reduction compared to placebo. Additionally, combination therapy of umeclidinium/vilanterol was significantly more effective than once-daily tiotropium, umeclidinium, and vilanterol monotherapies in lung function improvement
- The German Institute for Quality and Efficiency in Health Care found that combination umeclidinium/vilanterol was not shown to demonstrate benefit over tiotropium.
  - More specifically, in patients with moderate COPD and fewer than two exacerbations per year, umeclidinium/vilanterol did not show any differences in dyspnea and health-related quality of life compared to tiotropium

Arnuity
(fluticasone furoate)

- Fluticasone furoate (ICS) is indicated for maintenance treatment of patients with asthma age 12 years an older, available for delivery via the Ellipta® device.
- It is not indicated for acute bronchospasm,
- Dosing
  - 100 or 200 mcg inhaled by mouth once daily
  - Dose based on prior inhaled corticosteroid dose/ use
  - Starting dose is 100 mcg inhaled by mouth once daily for mild-moderate persistent asthma

Breo (fluticasone/vilanterol)

- Combination **fluticasone/vilanterol (ICS + LABA)** is indicated for the long-term, **once-daily** maintenance treatment of airflow obstruction in patients with COPD and asthma (18 years of age or older)
- Fluticasone/vilanterol is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations.

- Fluticasone/vilanterol is the first FDA-approved combination ICS/LABA to offer once-daily dosing for COPD. Currently, there are no head-to-head trials that have demonstrated superiority in the safety or efficacy of fluticasone compared to other ICS
- Dosing
  - Asthma – 100/25 mcg or 200/25 mcg 1 puff inhaled by mouth once daily
  - COPD – 100/25 mcg 1 puff inhaled by mouth once daily

Breo (fluticasone/vilanterol)

- One study found fluticasone/vilanterol significantly improved pulmonary function compared to placebo and fluticasone furoate monotherapy. Additionally, fluticasone/vilanterol demonstrated improved exacerbation rates compared to vilanterol monotherapy.
- Onset of action
  - Vilanterol also has a ***quicker onset*** of action compared to salmeterol.
- Despite the novel once-daily offering, the benefits of fluticasone/vilanterol over other twice-daily ICS/LABA combinations are still unclear.
- Comparison of fluticasone/vilanterol to vilanterol monotherapy in the reduction of exacerbation rates is difficult to discern, since vilanterol is not available as a monotherapy, and the same was not demonstrated for fluticasone monotherapy.
- More meaningful results would be obtained from a direct comparison of fluticasone/vilanterol to fluticasone/salmeterol (ie. Advair)

Incruse
(umeclidinum)

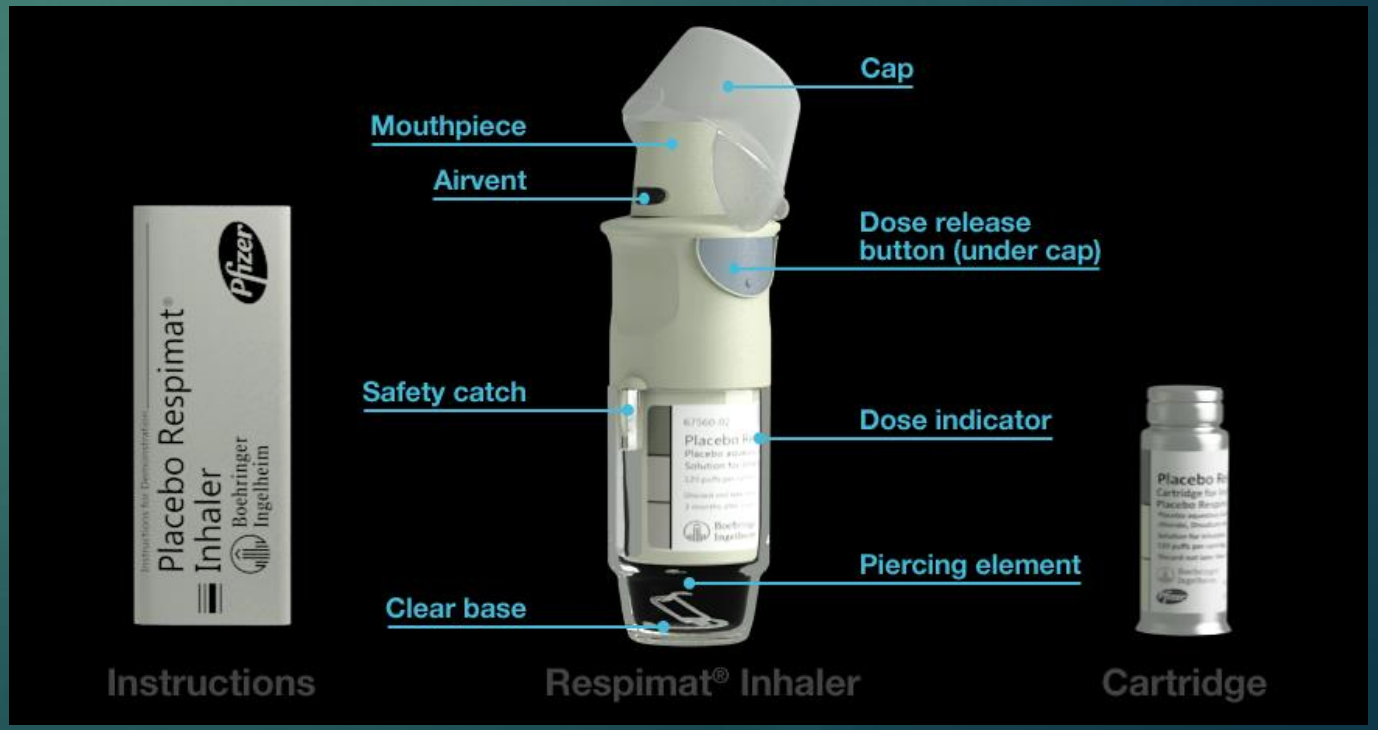
- **Umeclidinium** is a long-acting muscarinic antagonist **(LAMA)** approved for long-term maintenance of lung function in patients with COPD.
- Umeclidinium is indicated for once daily maintenance of COPD and received its indication based on clinical trials demonstrating improvements in FEV1 and FEV1/FVC in patients:
  - >40 years of age, currently smoking or with at least a 10-year pack history, a post-bronchodilator FEV1 <70% of expected, and a FEV1/FVC <70%
- Dosing
  - 62.5 mcg – 1 puff inhaled by mouth once daily

Incruse (umeclidinum)

- Study results included one randomized placebo-controlled, double-blind, parallel group trial, time to rehospitalization and next COPD exacerbation were delayed by approximately 100 days with umeclidinium compared to placebo.
- Signficiant differences in time to COPD exacerbation, and time to rehospitalization were not observed between umeclidinium and the combination of umeclidinium and vilanterol

Respimat Devices
Soft Mist

- Spiriva
  - 1.25 mcg – Asthma
  - 2.5 mcg – COPD
- Stiolto
- Striverdi



Respimat

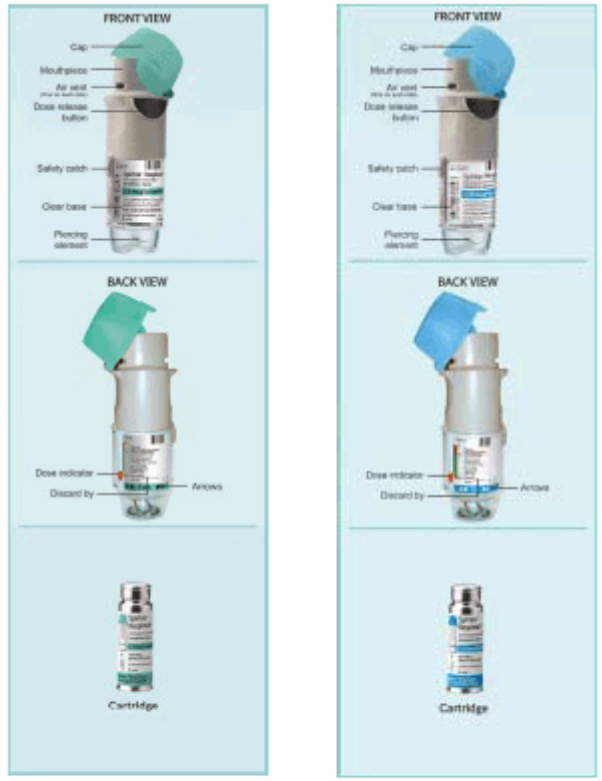
- Administration
  - Priming required!!
    - Point the inhaler towards the ground (away from your face) and press on the dose-release button until you see a spray.
    - Repeat 3 more times for a **total of 4 sprays** towards the ground. Your inhaler is ready to use.
  - When you haven't used in more than **3 days**, release **1** test spray towards the ground before using.
  - When you haven't If not used within **21 days**, release **4** test sprays towards the ground before using

Respimat

- Administration (cont.)
  - Press the small, grey safety catch button on the side and remove the clear base.
  - Write the discard date on the cartridge (3 months from 1st date of use).
  - Place the cartridge into the inhaler device and press into place until snug. Part of the cartridge (roughly 1/8 inch) will be visible at the bottom of the inhaler. This is normal.
  - Place the clear base back on the inhaler.
  - Holding the inhaler vertically as shown, twist the clear base in the direction of the white arrows until you hear a click. This will be approximately a half of a turn.
  - Flip the blue cap open.
  - Take a deep breath and exhale fully away from the inhaler. Place the inhaler to your mouth and form a seal around the mouthpiece with your lips. Be careful not to cover the air vents on the sides with your mouth. Take a deep, slow breath in. Remove the inhaler from your mouth and hold your breath for 10 seconds or less, however long is comfortable. Recap the inhaler once complete.
- Dose indicator
  - Indicator will move into the red zone when there are ***7 days*** left of medication

Spiriva Respimat
(tiotropium bromide)

- Tiotropium is a **LAMA** indicated for long-term, **once-daily** maintenance bronchodilator treatment of airflow obstruction in patients with COPD.
- There are 2 available strengths
  - 1.25 mcg per 2 actuations – Asthma (Blue cap)
  - 2. 5 mcg per 2 actuations – COPD (Aqua cap)



Aqua Blue

Stiolto Respimat
(tiotropium/olodatero)

- Tiotropium/olodaterol is a **LAMA/ LABA** combination inhaler approved for the long-term maintenance of lung function in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema
- Tiotropium/olodaterol demonstrated improvement in forced expiratory volume (FEV1) and forced vital capacity (FVC) in patients:
  - 40 years of age or older, currently smoking or with at least a 10-year pack history, with moderate to severe COPD defined as a FEV1 of <80% than predicted, and FEV1/FVC of <70%.
- Dosing
  - 2.5 mcg/2.5 mcg – 2 puffs inhaled ONCE daily

Stiolto Respimat
(tiotropium/olodatero)

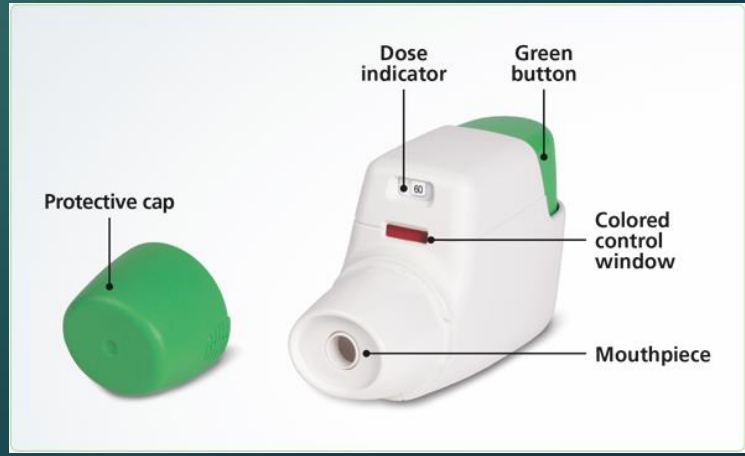
- Placebo-controlled trials remain the majority of the evidence supporting tiotropium/olodaterol with comparisons only available to the individual components of combination
- Improvements in the primary outcome of exercise capacity by approximately 50 seconds were observed after tiotropium/olodaterol administration when compared to placebo. Improvements of 0.26 L in FEV1were also observed when compared to placebo, however the long-term benefits of tiotropium/olodaterol are not available.

Striverdi Respimat
(olodaterol)

- Olodaterol is a **LABA** indicated for long-term, **once-daily** maintenance bronchodilator treatment of airflow obstruction in patients with COPD.
- Compared to placebo, olodaterol was shown to improve lung function, as evaluated by FEV1 area under the curve from 0 to 3 hours, and trough FEV1. Olodaterol demonstrated long-term efficacy and safety in patients with moderate to very severe COPD compared to placebo. These patients were allowed to continue their "usual-care" maintenance therapy other than other LABAs, including LAMAs, SAMAs, ICS, and methylxanthines.

Turdoza Pressair
(aclidinium bromide)

- Aclidinium bromide is a **LAMA** indicated for long-term maintenance therapy for COPD-associated bronchospasm.
- Aclidinium received FDA approval after studies demonstrated significant improvements in lung function, health status, and nighttime COPD symptom reduction in COPD patients compared to placebo. Patients enrolled in this trial were greater than 40 years of age, current or former smokers with at least a 10 pack-year history with moderate to severe COPD (30% < FEV1 < 80% predicted and post-bronchodilator FEV1/FVC < 70%)
- Dosing
  - 400 µg TWICE daily



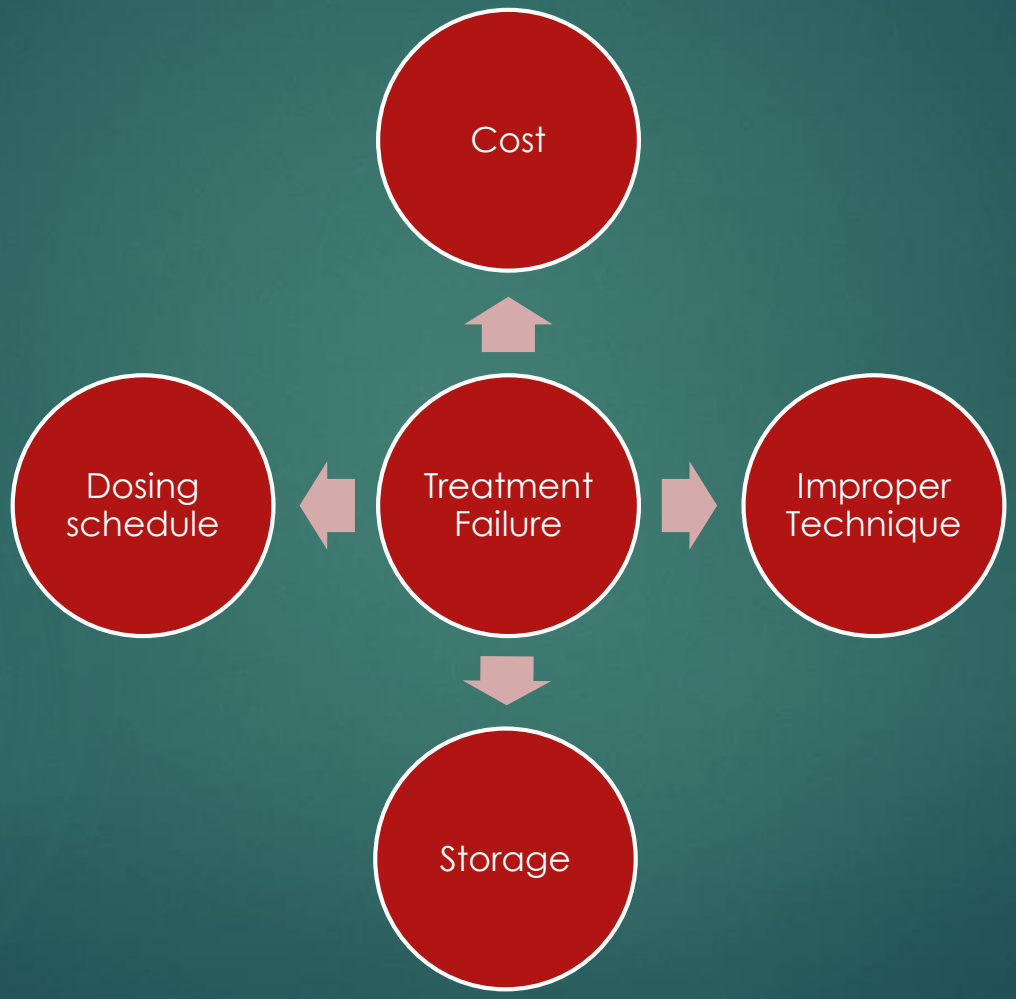
Turdoza Pressair
(aclidinium bromide)

- Administration
  - Remove the mouthpiece cap from the inhaler.
  - Press the green button all the way, and then release your finger from the inhaler.
  - When a green bar appears, this means the dose is ready. If it is red, the dose isn't ready quite yet.
  - Take a deep breath and breathe out completely away from inhaler.
  - Place your lips to the inhaler and form a seal around the mouthpiece. Take a deep, quick breath in until you hear a click. Hold your breath for roughly 10 seconds or however long is comfortable. Remove inhaler from your mouth and cover mouthpiece with dust cover.
- Dose indicator
  - Indicator will move into the red zone when there are ***7 days*** left of medication.

- Patient education is a critical factor in the use and misuse of medication inhalers. Inhalers represent advanced technology that is considered so easy to use that many patients and clinicians do not receive adequate training in their use. ***Between 28% and 68% of patients do not use metered-dose inhalers or powder inhalers well enough to benefit from the prescribed medication, and 39 – 67% of nurses, doctors, and respiratory therapists are unable to adequately describe or perform critical steps for using inhalers. Of an estimated $25 billion spent for inhalers, annually $5 – 7 billion is wasted because of inhaler misuse***. Reimbursement and teaching strategies to improve patient education could substantially reduce these wasted resources.

Respir Care 2005;50(10):1360 - 1374

Treatment Failure



Improper Technique

- https://www.youtube.com/watch?v=bDHEEV0M62Y
- Ask your patients
  - Can you show me how you are using the device?
  - Do you use a spacer?
  - Do you know how fast or slow to inhale the device
    - Many demo inhalers now contain an auditory sound when inspiratory rate is appropriate!
  - Do you understand why your are taking this medication
    - (ie. maintenance vs rescue)

Cost

- Cost continues to remain one of the top reasons for non-adherence and thus may lead to worsening of respiratory status and hospitalization

Cost

- Resources available
  - Manufacturer
    - Vouchers
      - Allow for 1-time fill for Medicare, uninsured and commercial insured patients
      - Billed as primary insurance ONLY (NOT processed with other insurances)
    - Coupons
      - Only can be used as SECONDARY insurance for cash and commercial paying individuals
    - Patient Assistance Programs (PAP)
      - Variable by manufacturer
      - Income dependent but patients can appeal due to financial hardship
      - May provide up to 1 year of medication at no charge!

Cost (cont.)

- Medicare/State
  - Medicare Extra Help
    - Many PAP's require letter of denial from Extra Help to be approved!
- Discount drug programs
  - GoodRx, LowestMeds, NeedyRx, America's Drug Card, Blink Health, Rx Outreach, AAA (for your car)
  - Through local pharmacy

*****See appendix for a comprehensive listing, website URL's and phone numbers*****

Dosing Schedule

- Adherence
  - Ask
    - Is the inhaler's administration schedule easy for the person to remember?
    - Does the patient take all of their medications once daily? Or multiple times per day?
    - How do you remember to take your medications?
    - Do you often forget to take your medication?

Storage

- Improper storage may lead to medication degradation, expiration and inadequate response leading to treatment failure
  - Ask
    - Where do you store your medication?
    - Do you keep your medications in an area which is either too hot, cold or humid?
    - How do you store your medication when traveling or going on a day trip?

Case studies

Let's get back into groups to review the patient cases together!

Case #1

- MS is a 72 y/o F with a past medical history significant for Type 2 DM, HTN, COPD, OSA, hyperlipidemia, Parkinson's disease and hyperthyroidism. She presents today to review her current inhaled maintenance inhalers. Upon further review she states that "they don't work". Below is a list of her current inhalers and how she takes them.

- Spiriva Handihaler
  - 1 capsule once daily
- Albuterol HFA
  - "as needed"
- Foradil Aerolizer
  - 1 capsule twice daily

Case #1

- What questions do you have for her?
- What potential barriers exist?
- Can you recommend alternate therapies?
- Would your recommendation change if she had memory impairment?

Case #2

- JR is a 64 y/o M presenting today for a hospital follow up after a recent COPD exacerbation. Past medical history significant for Type 2 DM with proliferative retinopathy OU, HTN, OA and RA. He reports that he recently started an inhaler about 3 weeks ago and found it difficult to use. He does not remember the names of his inhalers other than albuterol, only that he is instructed to take it once daily.

Case #2

- What questions do you have for her?
- What potential barriers exist?
- Can you recommend alternate therapies?
- Would your recommendation change if he did not have insurance?
- Would your recommendation change if he is turning 65 years old next week?

Questions??

Thank you!!

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