Treating COPD: The Road to Evidence-based Practice is Paved in GOLD

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Declarations

- Dr. Rosemary Henrich, DNP, FNP-BC has no conflicts of interest to declare.

- Dr. Amelia Schreibman, DNP, ANP-BC has no conflicts of interest to declare.

Objectives

- Participants will be able to compare the pharmacokinetics of three types of inhaled medication delivery systems – Metered Dose Inhaler (MDI) vs Dry Powder Inhaler (DPI) vs nebulized methods and name 4 factors that improve the effectiveness of each delivery system. (RX)

- Participants will be able to outline an EBP pathway for the initiation of specific pharmacological agents (SABAs, LABAs, Steroids, Anti-leukotrienes, Oxygen, Combination Inhalers) and the escalation or de-escalation of pharmacological treatments in COPD. (RX)

- Participants will be able to demonstrate how teach-back as an educational tool enhances patient education programs for the COPD patient.

COPD: Definition

► Chronic Obstructive Pulmonary Disease (COPD) is a common, preventable and treatable disease that is characterized by persistent respiratory symptoms and airflow limitation that is due to airway and/or alveolar abnormalities usually caused by significant exposure to noxious particles or gases.

► The most common respiratory symptoms include dyspnea, cough, wheeze and/or sputum production. These symptoms may be under-reported by patients.

► The main risk factor for COPD is tobacco smoking but other environmental exposures such as biomass fuel exposure and air pollution may contribute.

COPD vs ASTHMA vs ACOS

COPD

1. Onset in mid-life

2. Symptoms worsen slowly but also progressively

3. Usually associated with smoking/2nd hand smoke

ASTHMA

1. Usually young at diagnosis

2. Symptoms vary from day to day

3. Symptoms worse at night or early AM

4. Usually allergies also present

5. Family history of asthma

ACOS

1. Chest tightness present

2. Onset after age 40

3. History of smoking or other exposures

4. ?History of asthma with airway remodeling.

5. Exacerbations worse and 3 times more frequent.

*Pruitt, B. 2015

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► To provide a non-biased review of the current evidence for the assessment, diagnosis and treatment of patients with COPD.

► To highlight short-term and long-term treatment objectives organized into two groups:

  ➢ Relieving and reducing the impact of symptoms, and

  ➢ Reducing the risk of adverse health events that may affect the patient in the future.

► To guide symptoms assessment and health status measurement.

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Levels of Evidence: EBP

Table A. Description of levels of evidence

Evidence category	Sources of evidence	Definition
A	Randomized controlled trials (RCTs) Rich body of high quality evidence without any significant limitation or bias	Evidence is from endpoints of well-designed RCTs that provide consistent findings in the population for which the recommendation is made without any important limitations. Requires high quality evidence from ≥ 2 clinical trials involving a substantial number of subjects, or a single high quality RCT involving substantial numbers of patients without any bias.
B	Randomized controlled trials (RCTs) with important limitations Limited Body of Evidence	Evidence is from RCTs that include only a limited number of patients, post hoc or subgroup analyses of RCTs or meta analyses of RCTs. Also pertains when few RCTs exist, or important limitations are evident (methodologic flaws, small numbers, short duration, undertaken in a population that differs from the target population of the recommendation, or the results are somewhat inconsistent).
C	Non-randomized trials Observational studies	Evidence is from outcomes of uncontrolled or non-randomized trials or from observational studies.
D	Panel consensus judgment	Provision of guidance is deemed valuable but clinical literature addressing the subject is insufficient. Panel consensus is based on clinical experience or knowledge that does not meet the above stated criteria.

The Cornerstone of Treatment: Inhaled Medications

► 1. Deliver medications directly to the airways and lungs.

► 2. Reduce the dose of medication needed to treat the disease.

► 3. Reduce unwanted side effects associated with systemic medications.

Delivery Systems: Inhaled Rx

1. METERED DOSE INHALER (MDI)
2. DRY POWDER INHALER (DPI)
3. NEBULIZER
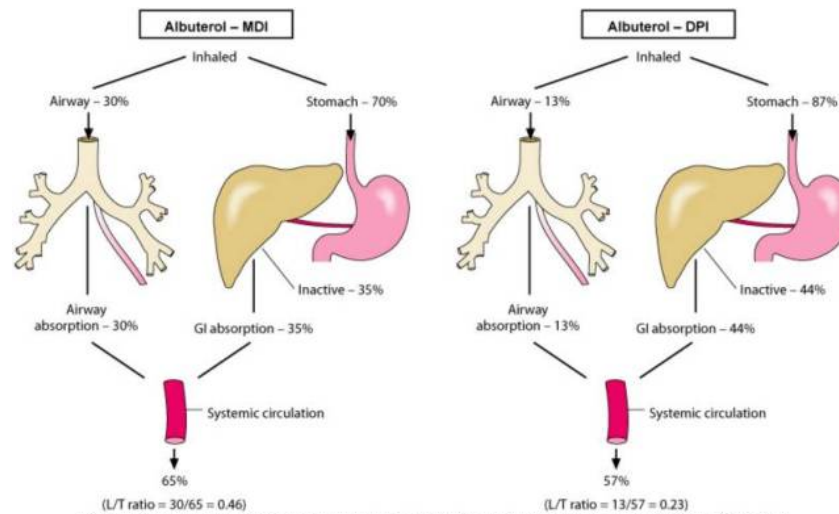4. SOFT MIST INHALER (SMI)

Pharmacokinetics
4 Phases

Absorption – Disintegration
Metabolism – Liver and GI enzymes
Distribution – Via bloodstream
Elimination – Mainly renal

* A CERTAIN AMOUNT OF AEROSOLIZED DRUG WILL ALWAYS IMPACT THE NASAL AND ORO-PHARYNX AND BE SWALLOWED!

MDI vs DPI Pharmacokinetics

Fig. 2-7. The lung availability/total systemic availability (L/T) ratio can quantify the efficiency of aerosol drug delivery to the respiratory tract by partitioning relative amounts from the gastrointestinal tract and from the respiratory tract (see text for explanation).

Nebulizer Pharmacokinetics

▶ 1. Only 5% of the medications used are deposited in the airways and lungs.

▶ 2. Efficacy dependent on patient's breathing patterns (Mouth Inhalation needed) and equipment.

▶ 3. Much of the drug settles in the reservoir.

▶ 4. Much also deposits on the rest of the equipment/tubing, patient's face.

▶ 5. Only recommended when other types of inhaled delivery systems cannot be used!

▶ https://www.degruyter.com/downloadpdf/books/9783110468007/97831104680 07-016/9783110468007-016.pdf

Factors that Improve Pharmacokinetics

Increase Delivery to the Lung

1. Improved delivery systems

2. Use a reservoir device-spacer

Improve ratio of lung vs GI Absorption

3. Timing of inhalations (receptors)

Reduce Swallowed Drug

▶ **1.** Use drugs with high first pass metabolism (Swallowed but quickly metabolized)

▶ **2.** Rinse mouth and throat after use

(Reduces amount of drug available to swallow)

Soft Mist Inhaler (SMI)

PROS:

1. 37% to 53% of the drug reaches the lower airways.

2. Ideal size of drug molecule 1-7Micron.

3. No propellants needed (Mechanical).

4. So a lower dose of drug is effective.

5. Slower delivery system – less oral intake.

▶ Panos, R. 2013

CONS:

1. Expensive! Not all plans will cover

2. Limited number of drugs available

3. More complicated and 'differs' from current MDIs.

Referenced Subjective Measurements Associated With Increased Exacerbations

mMRC: Dyspnea Scale

Dyspneic (breathlessness)on

- 1. strenuous exercise (0)
- 2. walking a slight hill (0)
- 3. walking on level ground, stops (1)
- 4. walking 100yds, must stop (2)
- 5. dressing, self-care (3)

CAT SCORE

- 1. Energy
- 2. Sleep quality
- 3. Mucous
- 4. Chest tightness
- 5. Cough
- 6. Activity

GOLD Category Changes: 2017

Category A

▶ 1. FEV 1 - <0.7 (+ COPD)

▶ 2. CAT <10; or mMRC 0-1

▶ 3. 0-1 Exacerbation over past year with no hospitalizations for COPD

Category B

▶ 1. FEV 1- <0.7 (+COPD)

▶ 2. CAT >10; or mMRC >2

▶ 3. 0-1 exacerbation over the past year no hospitalization for COPD.

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GOLD CATEGORY Changes: 2017

Category C

- 1. COPD Diagnosis confirmed

- 2. CAT <10; mMRC 0-1

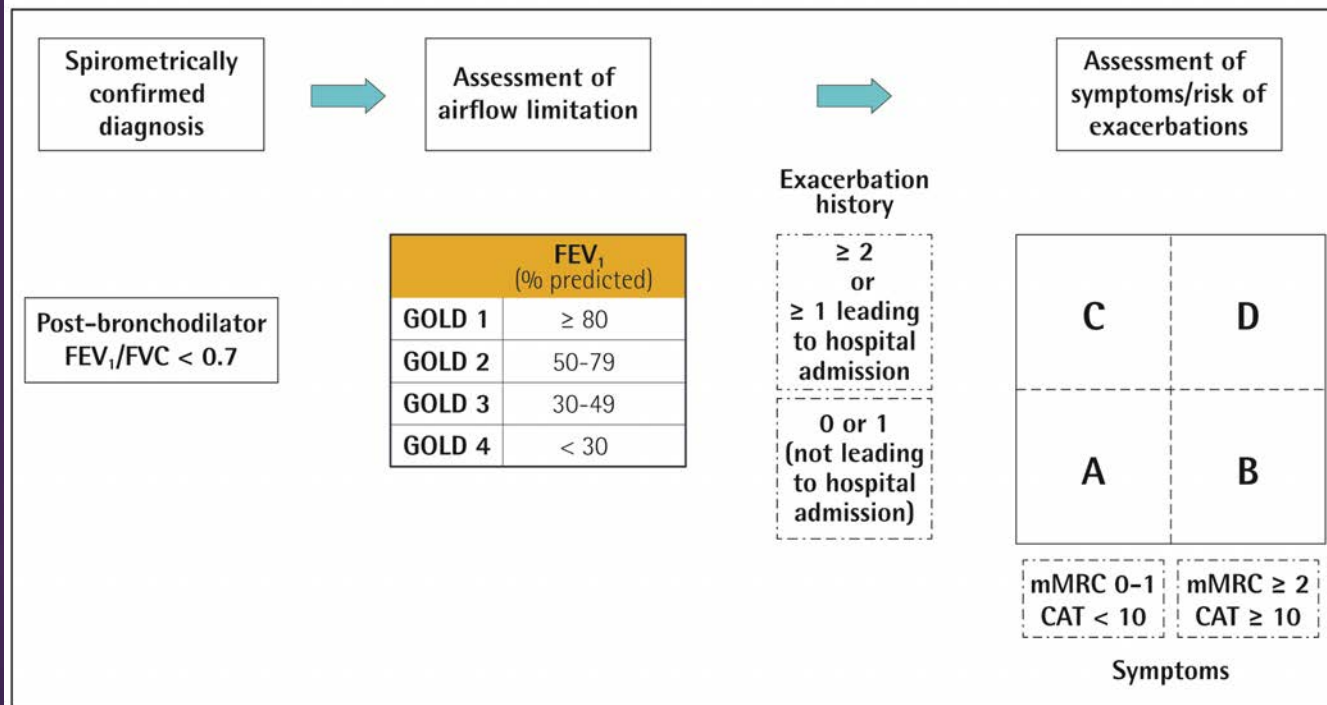- 3. Exacerbations: 2 or more this year or one hospitalization for COPD.

Category D

- 1. COPD Diagnosis confirmed

- 2. CAT >10; mMRC >2

- 3. Exacerbations 2 or more this year or one or more hospitalizations for COPD.

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ABCD Assessment Tool

Figure 2.4. The refined ABCD assessment tool

Spirometrically confirmed diagnosis → Assessment of airflow limitation → Assessment of symptoms/risk of exacerbations

Post-bronchodilator $FEV_1/FVC < 0.7$

	FEV_1 (% predicted)
GOLD 1	≥ 80
GOLD 2	50-79
GOLD 3	30-49
GOLD 4	< 30

Exacerbation history

≥ 2 or ≥ 1 leading to hospital admission

0 or 1 (not leading to hospital admission)

C	D
A	B

| mMRC 0-1 CAT < 10 | mMRC ≥ 2 CAT ≥ 10 |

Symptoms

Patient-Centered Factors

Co-morbidity

1. Recent MI <4 months

2. CHF NYHA Stage III or IV

3. Unstable angina

BODE Score

Body mass index

Obstruction degree

Dyspnea

Exercise

Age

1. Functional deterioration

2. Mental Capacity

*Individualized care

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Treatment for Stable COPD: Only Occasional Dyspnea

1. Short Acting Beta Agonist **(SABA)** Improve Symptoms /FEV1**(Evidence A)**

Relax smooth muscles in the airways. **Adverse:** Sinus tachycardia at rest/tremor

Duration: 4-6 Hours

2. Short Acting Muscarinic Agent **(SAMA) -** Improves Symptoms /FEV1**(Evidence A)** Block Broncho constrictors in the airway. **Adverse:** Dry mouth

Duration: 6 to 8 hours

3. Combination **(SABA/SAMA) -** Combo most effective **(Evidence A)**

Duration: 6 to 8 hours

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Treatment Escalation Needed
More Frequent Dyspnea

1. Long Acting Beta Agonist (LABA) **Evidence A**

2. Long Acting Muscarinic Agent (LAMA) Fewer exacerbations **Evidence A**

Fewer Hospitalizations **Evidence B**

3. Switch to Combination Agent (LABA/LAMA) if dyspnea worsens **Evidence A**

4. Inhaled medications preferred over oral **Evidence A**

5. Do not use theophylline unless long acting inhalers are unavailable or unaffordable

 Evidence B

(Global Initiative for Chronic Obstructive Lung Disease, 2017)

Severe/Very Severe COPD: Additions to Inhalers Consider

1. PDE4 Inhibitor Roflumilast: Chronic bronchitis - is effective **Evidence A**

*Side effects result in significant drop out rate (GI, Headaches)

  Cost $200/month

2. Macrolides for former smokers – is effective over one year **Evidence A**

Increased bacterial resistance and hearing loss.

- Rogliani, P., Calzetta, L., Cazzola, M., & Matera, M. G. (2016)

Monitoring and Follow-up

▶ Monitoring should focus on:

   ▶ Dosages of prescribed medications.

   ▶ Adherence to the regimen.

   ▶ Inhaler technique.

   ▶ Effectiveness of the current regime.

   ▶ Side effects.

▶ *Annual Spirometry - Treatment modifications should be recommended.*

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Risk Assessment for Exacerbation

► COPD exacerbations are defined as an acute worsening of respiratory symptoms that result in additional therapy.

► Classified as:

  ➢ Mild (treated with SABDs only)

  ➢ Moderate (treated with SABDs plus antibiotics and/or oral corticosteroids) or

  ➢ Severe (patient requires hospitalization or visits the emergency room). Severe exacerbations may also be associated with acute respiratory failure.

► Blood eosinophil count may also predict exacerbation rates (in patients treated with LABA without ICS).

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Managing COPD Exacerbations

Oxygen: Goal for saturation 88% to 92%.
Bronchodilators: Short acting beta-agonists with or with out anti-muscarinic preferred.
Systemic Corticosteroids: 40mgs daily for 5 days. Some authors up to 60mgs.

*2017 GOLD INITIATIVE FOR COPD

Managing COPD Exacerbations: When to add antibiotics

A. Patients with the three cardinal signs/symptoms:

1. Increased dyspnea
2. Increased sputum production
3. Increased appearance of purulent sputum.

B. Patients who require mechanical ventilation.

*(GOLD Initiative for COPD, 2017)

Hypoxemia and Oxygen

▶ **1.** Hypoxemia at rest: Long-term Oxygen (>15hours a day) indicated and prolongs life. **(Evidence Level A)**

▶ **2.** De-saturation **ONLY** with exercise or activity: Long term Oxygen **NOT** indicated. Will **NOT** prolong life, increase the time to next hospitalization, improve performance on a 6 minute walk. **(Evidence Level A)**

▶ **3.** Resting oxygenation at sea level does not preclude the possibility of desaturation during air travel. **(Evidence Level C)**

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Smoking Cessation

► Smoking cessation has the greatest capacity to influence the natural history of COPD.

► If effective resources and time are dedicated to smoking cessation, long-term quit success rates of up to 25% can be achieved.

Table 3.1. Brief strategies to help the patient willing to quit	
• ASK:	Systematically identify all tobacco users at every visit.
	Implement an office-wide system that ensures that, for EVERY patient at EVERY clinic visit, tobacco-use status is queried and documented.
• ADVISE:	Strongly urge all tobacco users to quit.
	In a clear, strong, and personalized manner, urge every tobacco user to quit.
• ASSESS:	Determine willingness and rationale of patient's desire to make a quit attempt.
	Ask every tobacco user if he or she is willing to make a quit attempt at this time (e.g., within the next 30 days).
• ASSIST:	Aid the patient in quitting.
	Help the patient with a quit plan; provide practical counseling; provide intra-treatment social support; help the patient obtain extra-treatment social support; recommend use of approved pharmacotherapy except in special circumstances; provide supplementary materials.
• ARRANGE:	Schedule follow-up contact.
	Schedule follow-up contact, either in person or via telephone.

Why COPD?

▶ **Impact** of COPD:

▶ Impacting 210 million people world wide, and 24 million in the USA (Lopez-Campos, Tan, & Soriano, 2016) and the only chronic illness on the rise, especially increased in women (Blanchette et al., 2014).

▶ 3 million deaths per year globally (WHO, 2015)

▶ U.S.: 3rd leading cause of death with150,000 deaths per year (WHO, 2017)

▶ Increased burden and use of resources with highest readmission rate of any chronic disease(Jinjuvadia, et al, 2017)

▶ Costing $32 billion annually in the US with a suspected increase to $49 billion by 2020 (Centers of Disease Control, 2018)

▶ Patients/families/significant others: physical and emotional

A Tale of 2 Projects

- ▶ COPD patients and their medication

- ▶ Project one looked at if age effected medication adherence

- ▶ Project two looked at exacerbation rates and medication adherence pre and post patient education of medications

RESULTS: Project 1

1. There was no impact related to age and compliance with inhaler use or the COPD treatment plan:

   a. 50% were sporadically non-adherent

   b. 55% were deliberately non-adherent

   c. 40% used their inhalers improperly

2. 93% of all participants learned to use their inhaler in one session, no matter their age

RESULTS: Project 2

▶ Pre education: 19 exacerbations in 17 patients

▶ Post education: 8 exacerbations in 8 patients

▶ Gender and Age influenced medication adherence

*Older elders (70-80) stopped medication because the felt worse

*Women stopped medication because they felt better

Education Tool: TEACH BACK TECHNIQUE

▶ Teach- back is a method to assess learner's understanding of education after being received by repeating the information back in their own words until mastery (Mahramus, Penoyer, Frewin, Chamberlin & Sole, 2014).

▶ Nurses can be particularly pivotal in this process by utilizing teach-back to reinforce content and the ability to assess the patients understanding of self-care concepts related to HF management (Mahramus et al., 2014).

Teach-back in Practice

- Use simple language, clearly explain the concept/demonstrate the process.

- Ask patients to use their own words to state understanding of the concept or demonstrate the process.

- Identify and correct misunderstandings and improper techniques and/or re-explain the concept/demonstrate the process again.

- Ask patients to re-explain/demonstrate again to ensure proper understanding of concepts/techniques.

- Repeat steps 3 and 4 until you are satisfied the patient understands or can safely perform the process demonstrated.

  (Wheeler, 2015)

Typical Teach-back Techniques

▶ Literature/print materials

▶ Placebo inhalers

▶ Discussion with patient/role play

Alternative Teach-back approaches

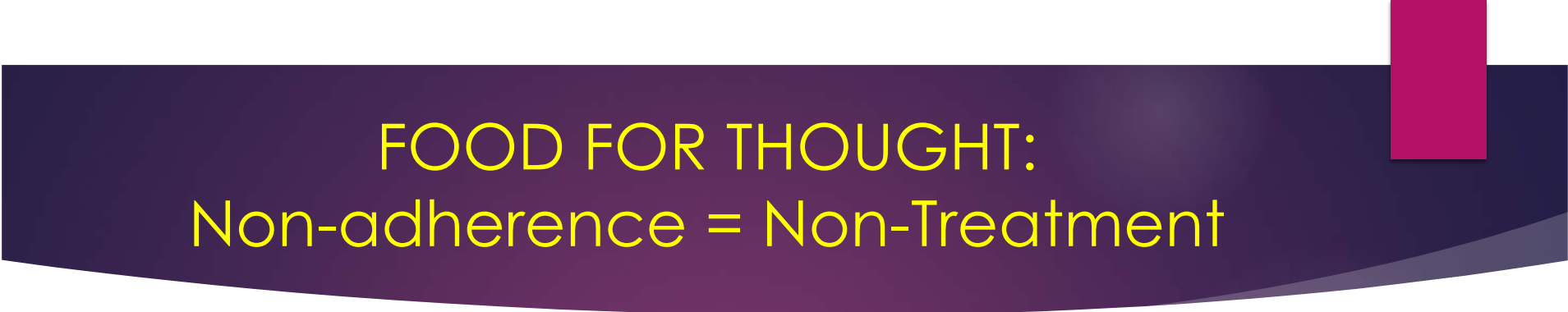- I-Pad, Lap top, Computer or Smart Phone with Videos via YouTube. Google, etc.

  a. Portability

  b. Access to different languages

  c. Both provider and patient have access

  d. Easily found at home or away

  e. Easy to follow

  f. Readily available/reusable to family and patients

PROJECT CONCLUSIONS

▶ Project 1: Up to 70% of all COPD patients do not use inhalers properly (Panos, 2016)

▶ Project 2: There is some component to non-adherence in **_every_** COPD patient

▶ Therefore…….

Patient/Provider Dilemma

FOOD FOR THOUGHT:
Non-adherence = Non-Treatment

- 70% of all COPD patients are NOT being treated for COPD!!!
- If patient's remain non-adherent they are not being treated for COPD!!!
- We failed our patients

Keys to Patient Adherence and Success

▶ Assess patient medication use/understanding at *every visit/encounter*

Remember the cycle……..

Assess patient:
Dx, Sx control/lung fxn, inhaler technique/med adherence

Refer to specialists as indicated

Adjust treatment:
Pharm and non-pharm strategies and treat modifiable risk factors like smoking, second hand smoke, obesity and co morbid conditions

Review Response:
Sx's, exacerbations, side-effects, patient satisfaction and lung function

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