Updates in Asthma and COPD management

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CSHP-OB Annual Conference

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Disclosures: Updates in Asthma & COPD

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CSHP-OB Annual Conference, November 16, 2019

I DO NOT have an affiliation (financial or otherwise) with for-profit/ commercial organizations.

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GeriMedRisk: Clinical Pharmacist

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Waypoint Centre for Mental Health Care

University of Toronto: Leslie Dan Faculty of Pharmacy, Adjunct Lecturer

Learning Objectives

At the end of this presentation, attendees should be able to:

1. Describe changes and updates in asthma management
2. Describe changes and updates in COPD management
3. Summarize the treatment approach to Asthma-COPD Overlap Syndrome (ACOS)
4. Apply these learnings and examine their impact on a case in a collaborative practice setting

Asthma

1. Describe changes and updates in asthma management
   a) What's new in GINA 2019- no SABA use alone
   b) Management of severe asthma- new biologics

What's new in GINA 2019?

- "**SABA-only treatment is no longer recommended** for treatment of asthma in adults and adolescents . This change was based on strong evidence that **SABA-only treatment increases the risk of severe exacerbations and asthma-related death**, and that adding any ICS significantly reduces the risk."
- "GINA now recommends that all adults and adolescents with asthma should receive either **symptom-driven** (in mild asthma) or **daily ICS-containing controller treatment**, to reduce the risk of severe exacerbations and asthma-related death..."

GINA (2019)

GINA 2019- background

- Mild asthma (symptoms <1x/wk in last 3 mo) at risk of serious AEs
  - 30–37% of adults with acute asthma
  - 16% of patients with near-fatal asthma
  - 15–20% of adults dying of asthma
- Regular use of SABA comes with many adverse effects
  - β-receptor downregulation, decreased bronchoprotection, rebound hyperresponsiveness, decreased bronchodilator response
  - Increased allergic response, and increased eosinophilic airway inflammation *(Aldridge, AJRCCM 2000)*
  - Dispensing ≥3 canisters/year (average 1.7 puffs/day) = ↑ risk ER visit, and ≥12 canisters/year= ↑ risk of death

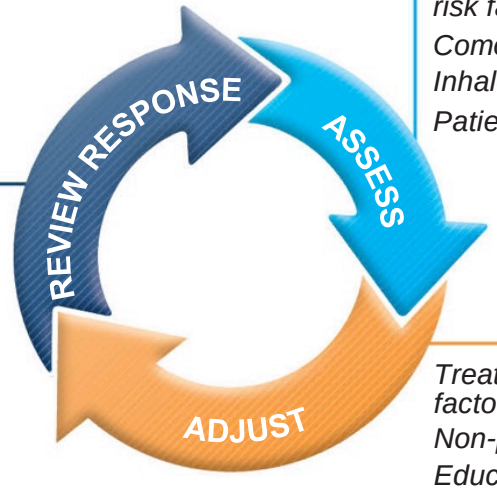
Dusser (2007), Hancox (2000), Aldridge (2000), Stanford (2012), Suissa (1994), GINA (2019), Reddel (2019)

What's new in GINA 2019?

Box 3-5A

Adults & adolescents 12+ years

Personalized asthma management:
Assess, Adjust, Review response



Confirmation of diagnosis if necessary
Symptom control & modifiable risk factors (including lung function)
Comorbidities
Inhaler technique & adherence
Patient goals

Symptoms
Exacerbations
Side-effects
Lung function
Patient satisfaction

Treatment of modifiable risk factors & comorbidities
Non-pharmacological strategies
Education & skills training
Asthma medications

Asthma medication options:
Adjust treatment up and down for individual patient needs

	STEP 1	STEP 2	STEP 3	STEP 4	STEP 5
PREFERRED CONTROLLER to prevent exacerbations and control symptoms	As-needed low dose ICS-formoterol *	Daily low dose inhaled corticosteroid (ICS), or as-needed low dose ICS-formoterol *	Low dose ICS-LABA	Medium dose ICS-LABA	High dose ICS-LABA Refer for phenotypic assessment ± add-on therapy, e.g.tiotropium, anti-IgE, anti-IL5/5R, anti-IL4R
Other controller options	*Low dose ICS taken whenever SABA is taken †*	*Leukotriene receptor antagonist (LTRA), or low dose ICS taken whenever SABA taken †*	*Medium dose ICS, or low dose ICS+LTRA #*	*High dose ICS, add-on tiotropium, or add-on LTRA #*	*Add low dose OCS, but consider side-effects*
PREFERRED RELIEVER	As-needed low dose ICS-formoterol *		As-needed low dose ICS-formoterol ‡		
Other reliever option	*As-needed short-acting β_2 -agonist (SABA)*				

* Off-label; data only with budesonide-formoterol (bud-form)
† Off-label; separate or combination ICS and SABA inhalers
‡ Low-dose ICS-form is the reliever for patients prescribed bud-form or BDP-form maintenance and reliever therapy
# Consider adding HDM SLIT for sensitized patients with allergic rhinitis and FEV$_1$ >70% predicted

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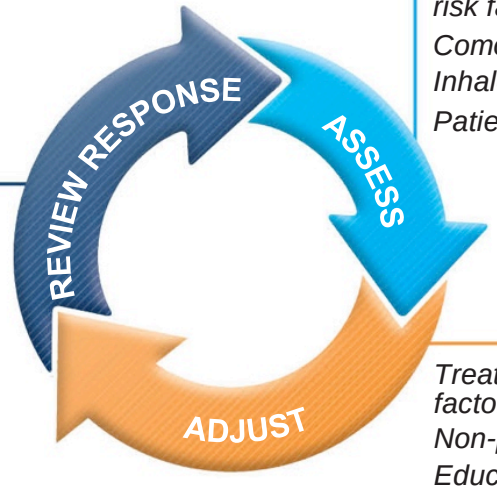

Treatment of modifiable risk factors & comorbidities
Non-pharmacological strategies
Education & skills training
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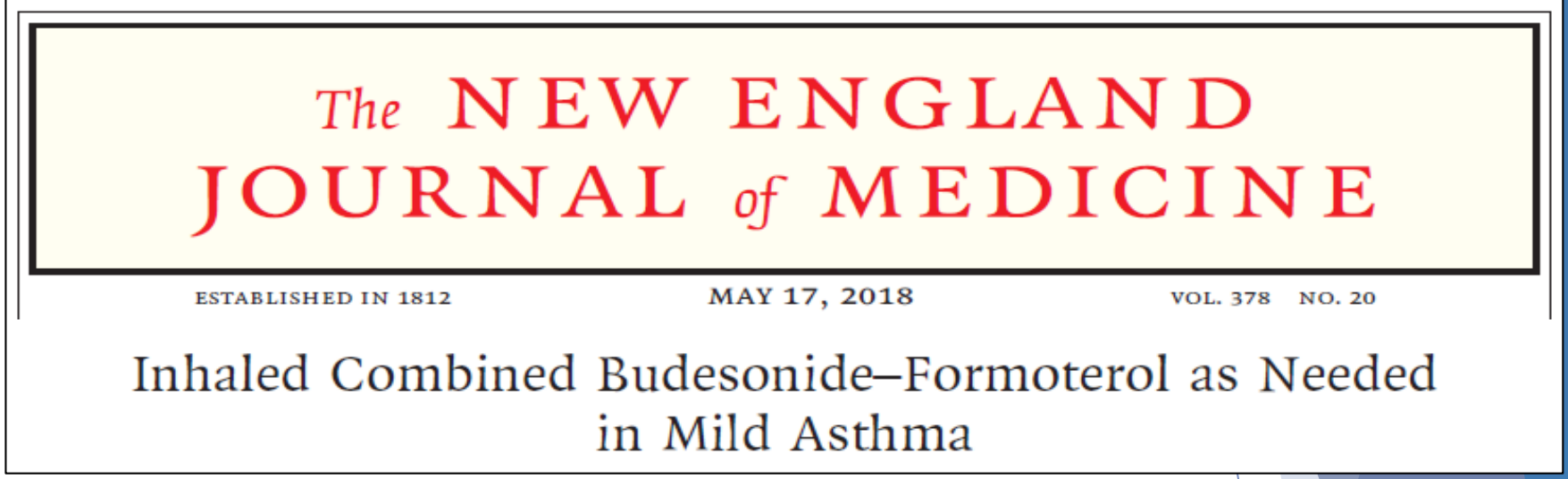
SYGMA-1



P: 3836 patients, ≥12 years old with mild asthma, 53 week

I: BUD-FOR group: BID placebo + budesonide/ formoterol PRN

C: TER group: BID placebo + terbutaline PRN

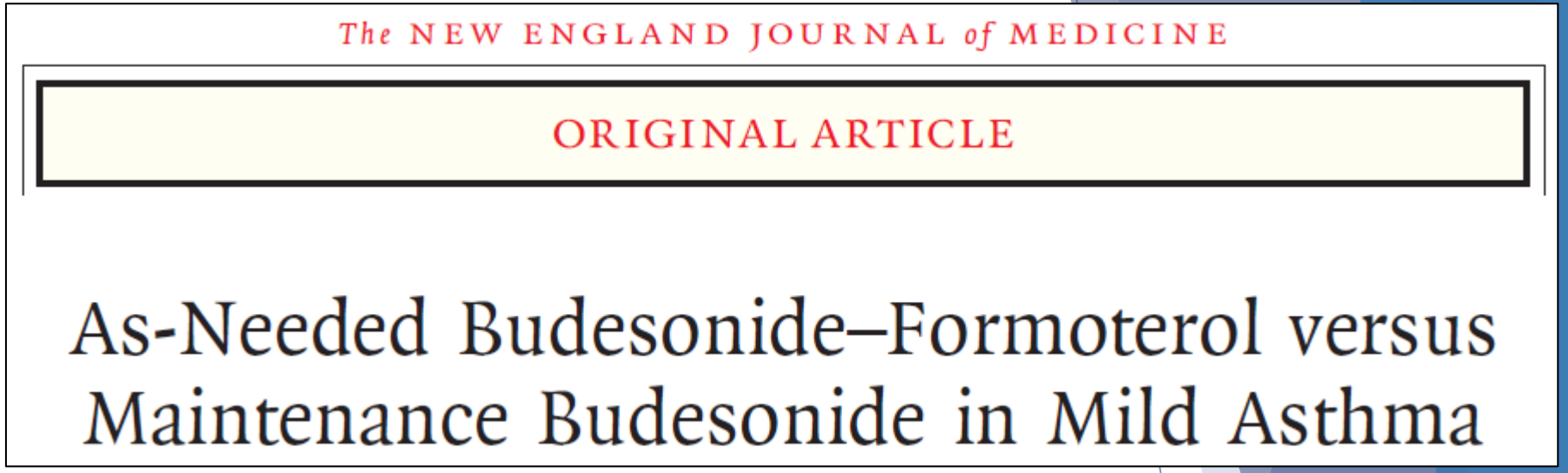
BUD maintenance group: BID BUD + terbutaline PRN

O: 1°: Mean % weeks with well-controlled asthma/pt: BUD-FOR 34.4% vs TER 31.1% (OR 1.14); vs BUD maintenance 44.4% (OR 0.64)

- 2°: Annual severe exacerbation rate: BUD-FOR 0.07 vs TER 0.2 (64% ↓)
- 2°: Mean ICS dose/d: 57 mcg vs 340 mcg (BUD-FOR vs BUD mnt -> 83% ↓)

O'Byrne (2018)

SYGMA-2



P: 4176 patients, ≥12 years old with mild asthma, 52 weeks

I: BUD-FOR group: BID placebo + budesonide/ formoterol PRN

C: BUD group: BID BUD + terbutaline PRN

O: 1°: severe exacerbation rate/ year: BUD-FOR 0.11 vs BUD 0.12 -> **non-inferior**

- 2°: Mean ICS dose/d: 66 mcg vs 267 mcg (BUD-FOR vs BUD mnt -> 75% ↓)
- 2°: ACQ-5 score: BUD ↓ by 0.11 units more than BUD-FOR (0.45 vs 0.35, $p<0.0001$), FEV_1 change from baseline: less with BUD-FOR vs BUD

Bateman (2018)

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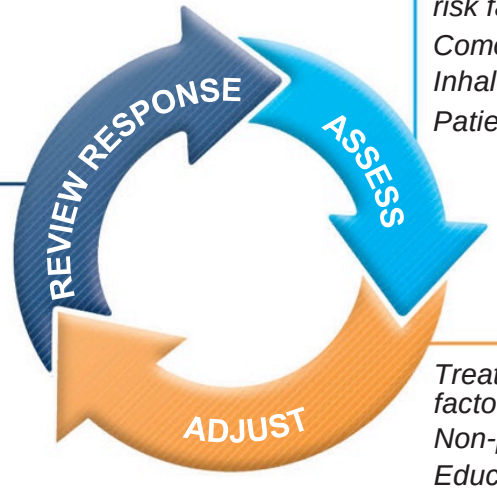

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Assessment of asthma control

Asthma Symptoms	Well controlled	Partly controlled	Uncontrolled
Daytime symptoms >2x/wk	None	1-2 of these	3-4 of these
Any night awakenings			
PRN use >2x/wk			
Activity limitation			

GINA (2019), Reddel (2019)

Assessment of uncontrolled asthma

1) Check inhaler technique and adherence/ frequency/ barriers to use
2) Confirm diagnosis of asthma
3) Remove potential risk factors (smoking, B-blockers, NSAIDs, allergens) and comorbidities (rhinitis, GERD, depression, etc)
4) Consider step-up therapy, using shared decision making
5) If uncontrolled after 3-6 months or step 4 (earlier if severe symptoms or doubts about diagnosis), refer to specialist

GINA (2019)

Asthma

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Management of severe asthma

- Who?
  - 3.7% of patient with asthma
- What is it?
  - Defined as step 4-5 + poor symptom control + good adherence/inhaler use
- What about the patient experience?
  - Heavy burden of symptoms
  - Exacerbations
  - Medications side effects (often due to oral corticosteroid requirements)

GINA (2019)

Management of severe asthma

1) Assess for type 2 inflammation
   - blood/ sputum eosinophils
   - Fractional concentration of exhaled NO
   - Clinically allergy-driven
   - Need for maintenance OCS
2) Review adherence, increase ICS x 3-6 months, consider:
   - Aspirin-exacerbated (AERD): ICS, LTRA, ASA desensitization
   - Allergic bronchopulmonary aspergillosis (ABPA): OCS +/- itraconazole
   - Chronic rhinosinusitis: intranasal corticosteroids
   - Atopic dermatitis: topical steroidal or non-steroidal agents

GINA (2019)

Management of severe asthma

3) Is add-on type 2 biologic affordable? (also consider frequency, route, patient preference when choosing)
   - Anti-IgE
     - omalizumab
   - Anti-IL5/ Anti-IL5R
     - mepolizumab, reslizumab, benralizumab
   - Anti-IL4R
     - dupilumab
   - Anti-IL13*
     - lebrikizumab, tralokinumab
   - Anti-TSLP (thymic stromal lymphopoetin)*
     - Tezepelumab
4) Trial for at least 4 months, reassess q3-6months

GINA (2019), Edris (2019)

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2. Describe changes and updates in COPD management
   a) GOLD 2019 changes
   b) GOLD vs CTS ~~2017~~ 2019 statement
   c) Beta-blockers in COPD
   d) New inhalers available

GOLD 2019- Initial Pharmacotherapy

What's New?

No step up/ down

≥ 2 moderate exacerbations or ≥ 1 leading to hospitalization	Group C LAMA	Group D LAMA or LAMA + LABA* or ICS + LABA ** *consider if highly symptomatic **consider if eos ≥ 300
0 or 1 moderate exacerbations (not leading to hospital admission)	Group A A bronchodilator	Group B A Long Acting Bronchodilator (LAMA or LABA)
	mMRC 0-1/ CAT < 10	mMRC ≥ 2/ CAT ≥ 10

No spirometry

GOLD (2019)

GOLD 2019- Management Cycle

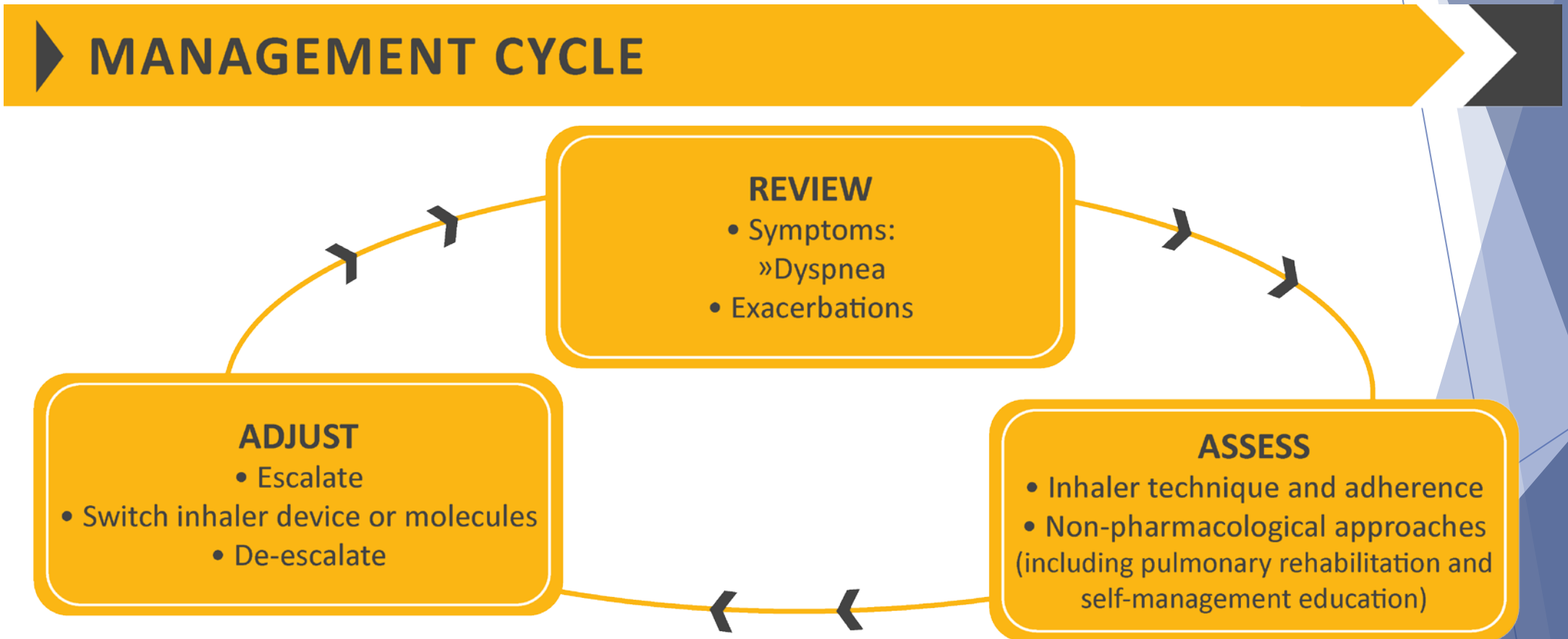
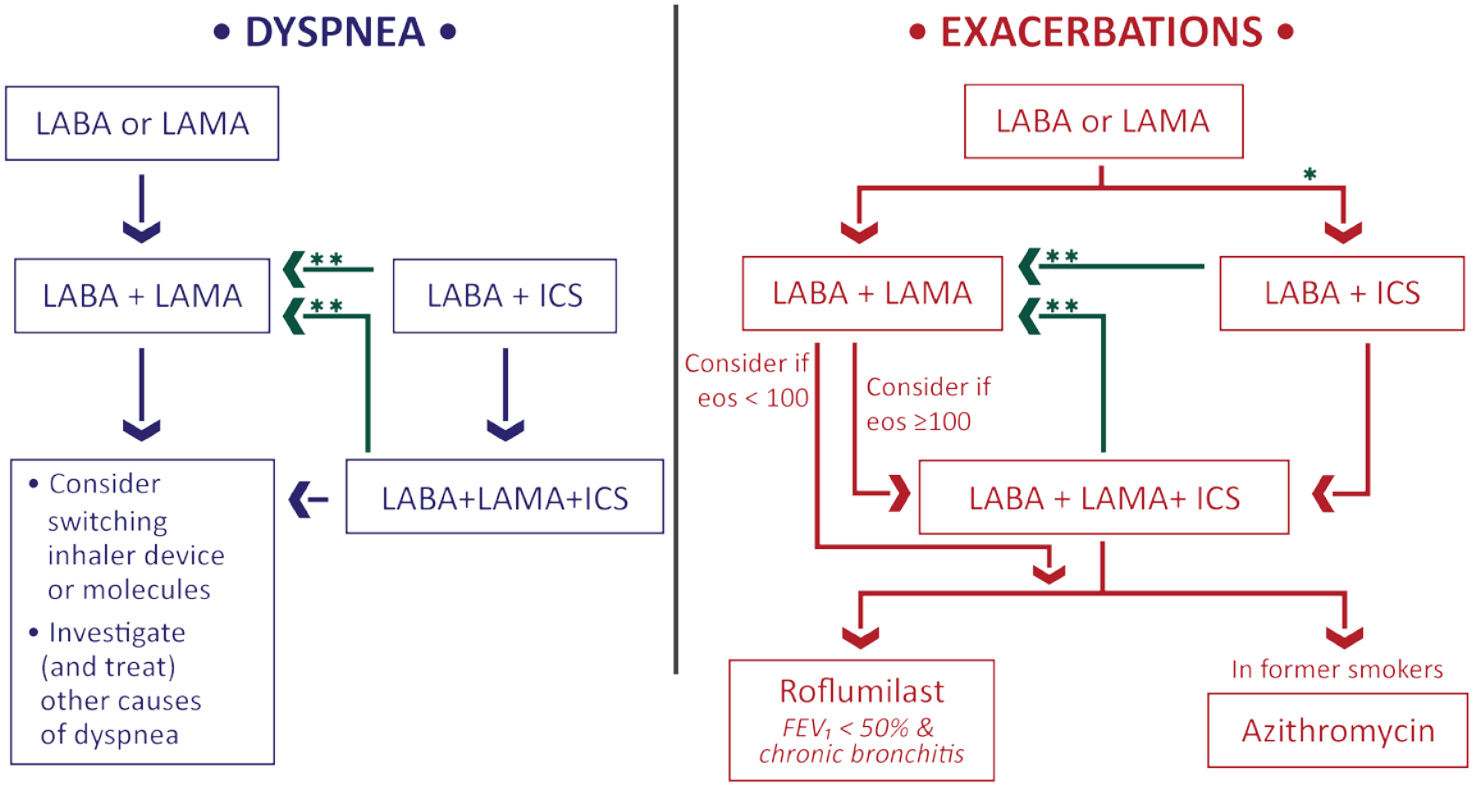


FIGURE 4.2

GOLD (2019)

FOLLOW-UP PHARMACOLOGICAL TREATMENT

1. **IF RESPONSE TO INITIAL TREATMENT IS APPROPRIATE, MAINTAIN IT.**
2. **IF NOT:**
   - ✓ Consider the predominant treatable trait to target (dyspnea or exacerbations)
     - Use exacerbation pathway if both exacerbations and dyspnea need to be targeted
   - ✓ Place patient in box corresponding to current treatment & follow indications
   - ✓ Assess response, adjust and review
   - ✓ These recommendations do not depend on the ABCD assessment at diagnosis



eos = blood eosinophil count (cells/µL)

**** Consider if eos ≥ 300 or eos ≥ 100 AND ≥2 moderate exacerbations / 1 hospitalization***

***** Consider de-escalation of ICS or switch if pneumonia, inappropriate original indication or lack of response to ICS***

FIGURE 4.3

GOLD 2019- Adjust Pharmacotherapy

GOLD (2019)

GOLD- other non-pharmacologic treatments

- Self-management education
- Physical Activity/ exercise training
- Nutritional Support
- Smoking cessation
- Vaccinations
- Pulmonary rehabilitation
- Oxygen therapy

GOLD (2019)

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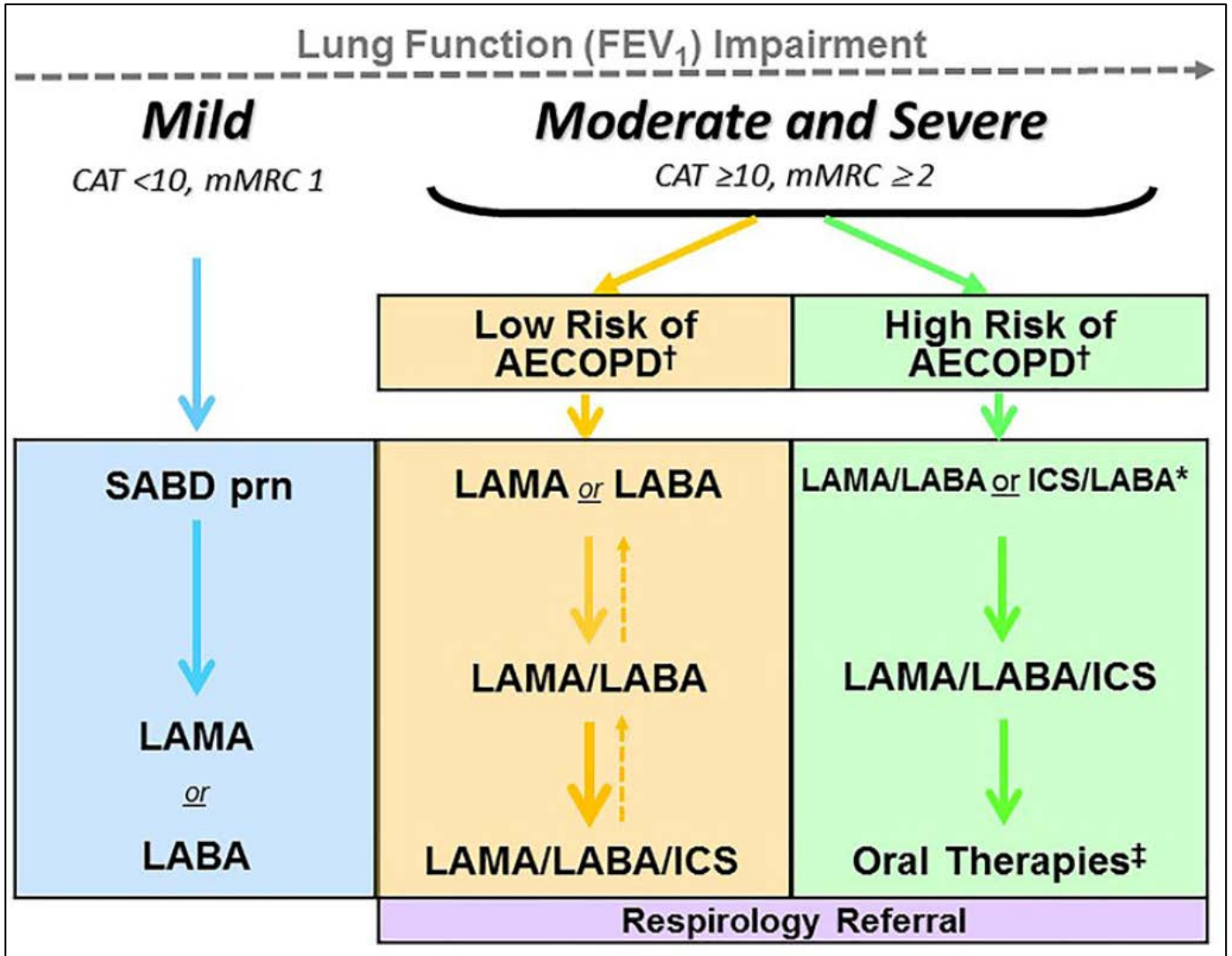
CTS Clinical Practice Guideline: Pharmacotherapy in patients with COPD- 2019 update of the evidence

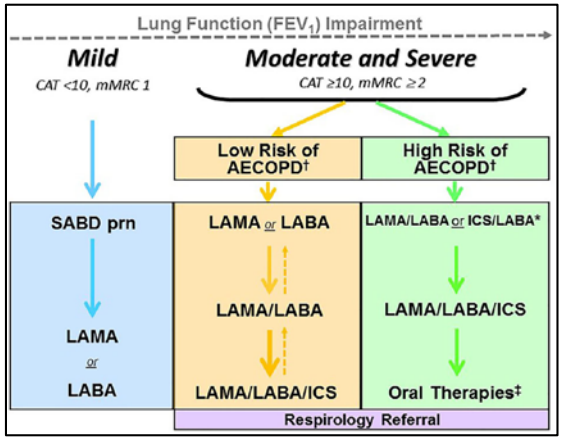


†Low= ≤ 1/yr, High= ≥1-2/yr

*blood eosinophils >300mcL

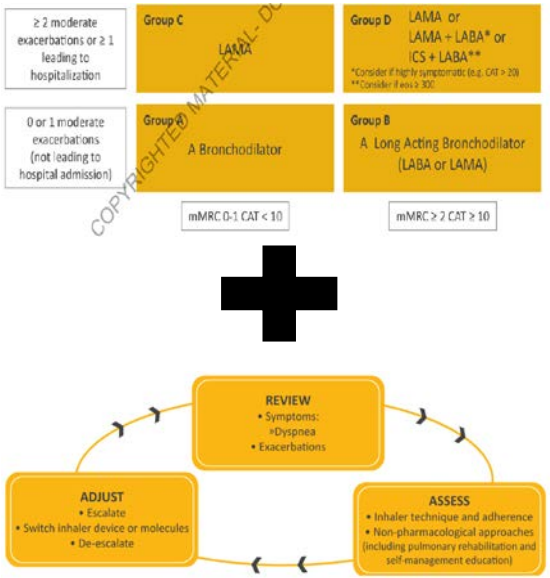
††Roflumilast, azithromycin, NAC

CTS (2019)



CTS 2019

VS



GOLD 2019

- Similar stepwise approach
- GOLD has separated initial choice vs management cycle
- GOLD has ICS in “Group D” for initial- both highlight ICS in patients with frequent exacerbations
- Both introduce eosinophil use to identify appropriateness for ICS use
- Both include de-escalation suggestions for low risk exacerbations
- CTS 2017 incorporated ACOS and tried to address management in its COPD guidelines

CTS (2017), GOLD (2019), CTS (2019)

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Beta-blockers in COPD

- Long standing concern and controversy using beta-blockers in obstructive lung disease
- Specifically that they can result in bronchoconstriction and worsening shortness of breath

What is the evidence?

Beta-blockers in COPD

Nielsen at al (2019): multiple adjusted cox regression models

- P: 301,542 pts (BB), >1 million pts (other BP meds), no Hx COPD hospitalization, 30-90 years, Danish registry data
- I: >6 months B-blocker prescription
- C: >6 months any other antihypertensive
- O: B-blocker group had lower risk of COPD hospitalization, HR 0.8
  - Better outcomes in subgroups: ischemic heart disease, cardiac arrhythmias, asthma, hypertension, diseases of pulmonary circulation (PE or cor pulmonale)
  - All- cause mortality (HR 0.69*) and risk of COPD death (HR 0.56) lower in B-blocker group

Nielsen (2019)

Beta-blockers in COPD

Dransfield et al (Oct 20, 2019): prospective, randomized trial

- P: 532 pts, 40-85 years old, with clinical history COPD,FEV_1=41+/-16% predicted, exacerbation in last year or use of oxygen, no indication for B-blocker
- I: ER metoprolol (25 mg, 50 mg, or 100 mg)
- C: matched placebo
- O: 1°- no significance in time to 1st COPD exacerbation (BB: 202 days, placebo: 222 days)
  - Terminated early due to power analyses and safety concerns
  - Metoprolol ↑ risk of exacerbation needing hospital (HR 1.91)
  - Metoprolol group: 11 deaths (4.1%) vs placebo: 5 deaths (1.9%)

Dransfield (2019)

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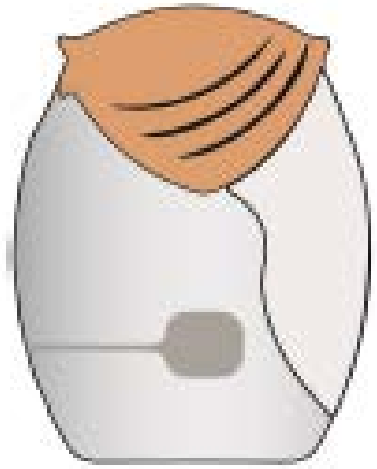
Inhalers available

							
	MDI	**Diskus**	**Aerolizer/ Turbuhaler**	**Breezhaler**	**Genuair**	**Respimat**	**Ellipta**
SABA	**Ventolin**	**Ventolin**	**Bricanyl**			**Combivent**	
SAMA	**Atrovent**						
LABA		**Serevent**	**Foradil**	**Onbrez**		**Striverdi**	
LAMA				**Seebri**	**Tudorza**	**Spiriva**	**Incruse**
LABA/LAMA				**Ultibro**	**Duaklir**	**Inspiolto**	**Anoro**
LABA/ICS	**Advair**	**Advair**	**Symbicort**				**Breo**
LABA/LAMA/ICS							**Trelegy**

Lung Association (2018), GOLD (2019), CTS (2017)

Other news…



- TRELEGY: LABA/LAMA/ICS (vilanterol/ umeclidinium/ fluticasone furoate)
- **Covered** via LU: 567
  - long-term, once daily, maintenance treatment of COPD and to reduce exacerbations of COPD in patients who require a combination ICS/ LAMA/ LABA

- Others triple therapy inhalers likely to come
- Inhaled PDE-4 inhibitor(s) in the pipeline

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3. Summarize the treatment approach to Asthma-COPD Overlap Syndrome (ACOS)

Asthma-COPD Overlap Syndrome (ACOS)

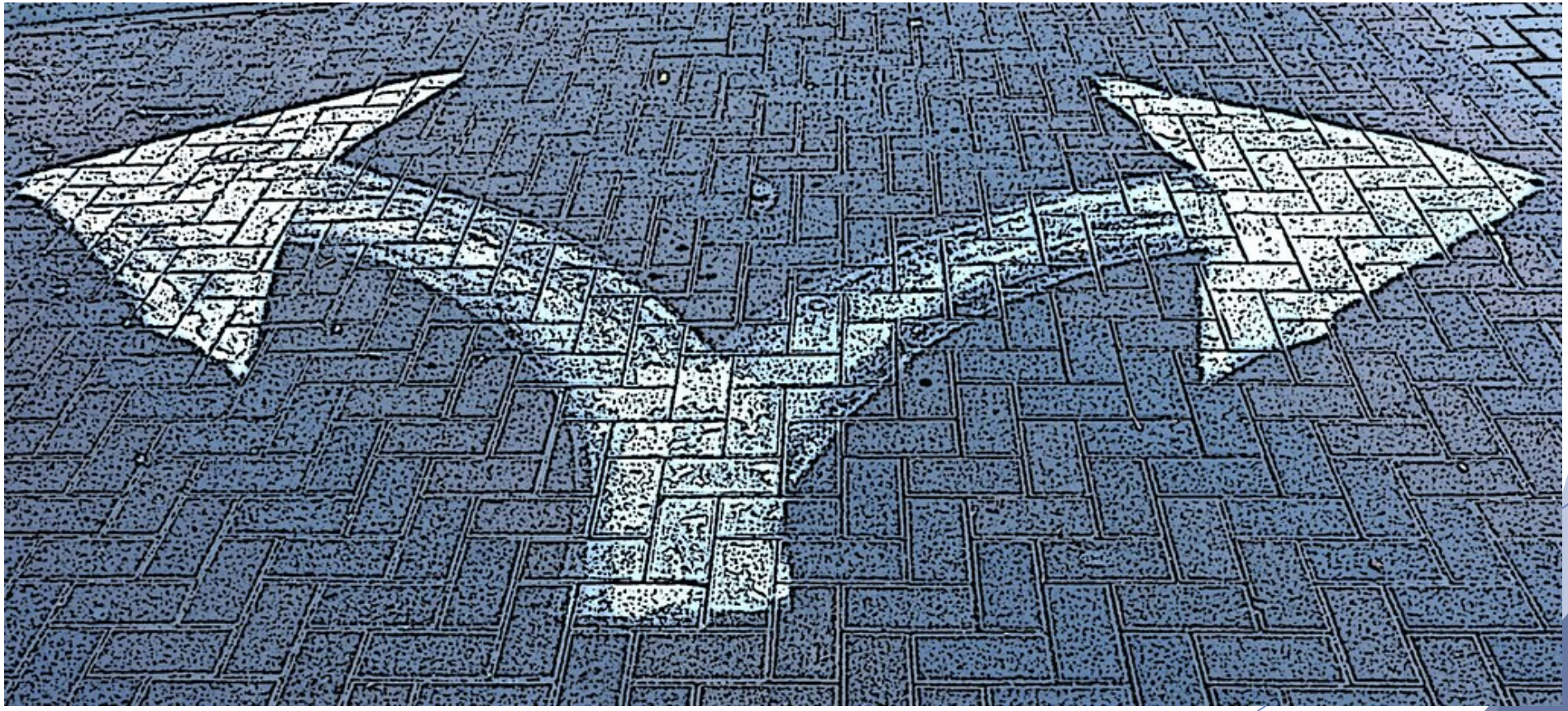
What is it? (proposed 2017 CTS definition)

"Characterized by post bronchodilator airflow limitarion that is not fully reversible, in symptomatic patients with risk factors for COPD and who have clinical features of both asthma and COPD."

CTS (2017)

Asthma-COPD Overlap Syndrome (ACOS)

- The dilemma



ACOS: assessment

Assessment:

1) Risk factors for COPD
2) Symptoms compatible with COPD
3) History of allergy/ atopy, asthma
4) Pre and post bronchodilator spirometry

CTS (2017)

ACOS: diagnosis (CTS)

Required:

1. Diagnosis of COPD (RF, symptoms, spirometry)
2. History of asthma (previous diagnosis, current symptoms)
3. Persistent fixed airflow limitation on spirometry ($FEV_1/FVC < 0.7$)

Supportive:

1. Acute bronchodilator improvement in FEV_1 of 12% and >200 mL
2. Sputum eosinophils > 3%
3. Blood eosinophils > 300 cells/μL

CTS (2017)

ACOS: diagnosis (GOLD)

STEP 2 SYNDROMIC DIAGNOSIS IN ADULTS

(i) Assemble the features for asthma and for COPD that best describe the patient.
(ii) Compare number of features in favor of each diagnosis and select a diagnosis

Features: if present suggest	ASTHMA	COPD
Age of onset	❑ Before age 20 years	❑ After age 40 years
Pattern of symptoms	❑ Variation over minutes, hours or days ❑ Worse during the night or early morning ❑ Triggered by exercise, emotions including laughter, dust or exposure to allergens	❑ Persistent despite treatment ❑ Good and bad days but always daily symptoms and exertional dyspnea ❑ Chronic cough & sputum preceded onset of dyspnea, unrelated to triggers
Lung function	❑ Record of variable airflow limitation (spirometry or peak flow)	❑ Record of persistent airflow limitation ($FEV_1/FVC < 0.7$ post-BD)
Lung function between symptoms	❑ Normal	❑ Abnormal
Past history or family history	❑ Previous doctor diagnosis of asthma ❑ Family history of asthma, and other allergic conditions (allergic rhinitis or eczema)	❑ Previous doctor diagnosis of COPD, chronic bronchitis or emphysema ❑ Heavy exposure to risk factor: tobacco smoke, biomass fuels
Time course	❑ No worsening of symptoms over time. Variation in symptoms either seasonally, or from year to year ❑ May improve spontaneously or have an immediate response to bronchodilators or to ICS over weeks	❑ Symptoms slowly worsening over time (progressive course over years) ❑ Rapid-acting bronchodilator treatment provides only limited relief
Chest X-ray	❑ Normal	❑ Severe hyperinflation

NOTE: • These features, if present, best distinguish between asthma and COPD. • Several positive features (3 or more) for either asthma or COPD suggest that diagnosis. • If there are a similar number for both asthma and COPD, consider diagnosis of ACOS

DIAGNOSIS	Asthma	Some features of asthma	Features of both	Some features of COPD	COPD
CONFIDENCE IN DIAGNOSIS	Asthma	Possible asthma	Could be ACOS	Possibly COPD	COPD

GOLD/ GINA ACOS (2015)

ACOS: pharmacotherapy

If one syndrome predominates, treat as such and follow

- If asthma: ICS initial therapy +/- LABA depending on severity
- If COPD: LAMA or LABA initial therapy (+/- combination if severe)
- If truly overlapping features of both:
  - ICS
  - usually with LABA (default to asthma- not LABA monotherapy)
  - Consider addition of LAMA, depending on severity/ response

CTS (2017), GOLD/ GINA ACOS (2015)

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4. Apply these learnings and examine their impact on a case in a collaborative practice setting

Case: Mr SB

78M in FHT, follow up after 4 day admission for AECOPD/ CHFe

- COPD hx: on LAMA (Spiriva Respimat), LABA/ICS (Symbicort), SABA
- Non-adherent to LABA/ICS or SABA due to device
- 1st exacerbation, thinks he got a cold from his granddaughter

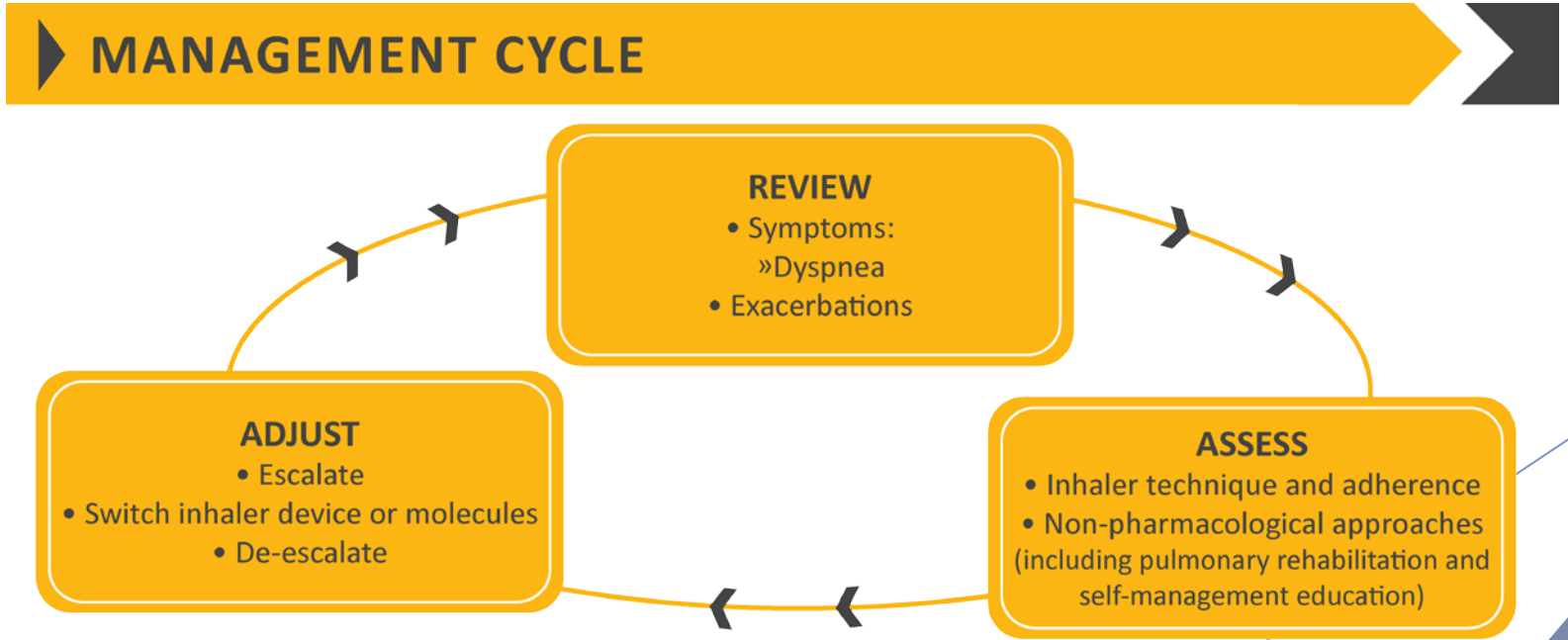

FIGURE 4.2

Collaborative Practice component

- Review
  - Symptoms: dyspnea vs exacerbations
  - COPD diagnosis confirmation
- Assess
  - Inhaler technique and adherence
  - Non-pharm: smoking cessation, self-management education, vaccinations, pulmonary rehab
- Adjust
  - Escalate vs de-escalate vs switch inhaler device

Learning Objectives

1. Describe changes and updates in asthma management
   a) What's new in GINA 2019- no SABA use alone
   b) Management of severe asthma- new biologics
2. Describe changes and updates in COPD management
   a) GOLD 2019 changes
   b) GOLD vs CTS 2017 statement
   c) New inhalers available
   d) Beta-blockers in COPD
3. Summarize the treatment approach to Asthma-COPD Overlap Syndrome (ACOS)
4. Apply these learnings and examine their impact on a case in a collaborative practice setting

Questions?

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