



# NACE *Conversations* in Pulmonology 2019

## Final Live Outcomes Report



## The Role of Biologic Therapy in Severe Asthma: A Shifting Treatment Paradigm

Sanofi Genzyme and Regeneron Pharmaceuticals • IME-2018-13285

October 1, 2019





# The Role of Biologic Therapy in Severe Asthma: A Shifting Treatment Paradigm



468 Participants



1 Activity



468 certificates issued to date

The findings reveal that this education has the potential to impact

## 273,529

patients with asthma on an annual basis.

887-1,084 Patients Weekly

### 2019 Conversations Activity

### Date

Conversations in Pulmonology 2019

3/30/19

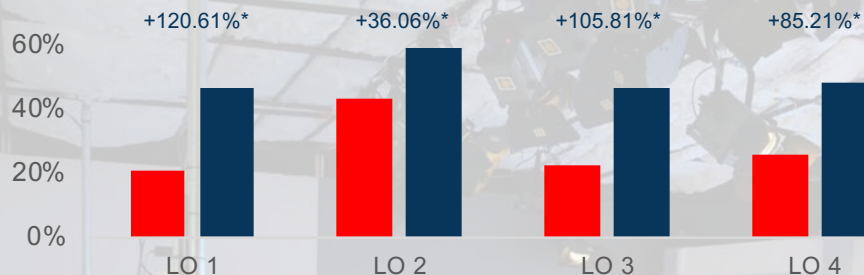
### The Role of Biologic Therapy in Severe Asthma: A Shifting Treatment Paradigm



#### COURSE SUMMARY

Cost: Free  
Start Date: 06/01/2019  
Expiration Date: 05/31/2020  
Target Audience: Pulmonologists, Primary Care Physicians, Nurse Practitioners, Physician Assistants  
Format: Webcast  
Estimated Time To Complete CME Activity: 1 hour  
Credits: 1.0 AMA PRA Category 1 Credit™, 1.0 AANP Contact hour which includes 0.75 pharmacology hours  
Hardware/Software Requirements: Any web browser

## Learning Gains Across Objectives



- ❖ **LO 1:** Describe the current concepts in the pathophysiology of asthma and type 2 inflammation, and the implications of biologic therapies in the era of precision medicine
- ❖ **LO 2:** Discuss the clinical assessment of asthma control and risk factors for poor asthma outcomes
- ❖ **LO 3:** Individualize the treatment approach for patients with moderate to severe asthma while recognizing appropriate candidates for biologicals and other advanced therapies
- ❖ **LO 4:** Recognize the impact of comorbid conditions on asthma control and evidence - based approaches to their treatment

## Persistent Learning Gaps/Needs

### Importance of confirming diagnosis for patients with apparent uncontrolled asthma

On a Competence item asking learners to identify the appropriate next step for a patient with a long history of diagnosed asthma and daily symptoms, learners struggled at Post-Test to correctly identify the need to confirm the asthma diagnosis.

### Treatment selection for asthma patients unmanaged by current therapies

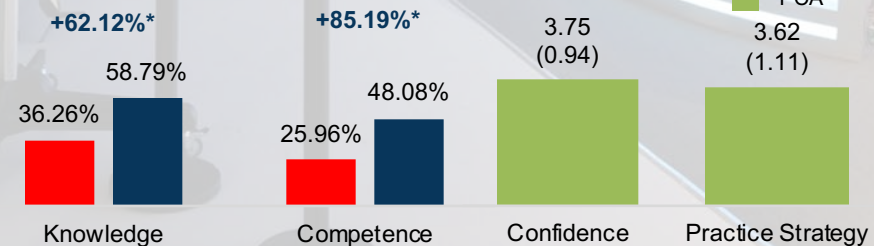
On Knowledge and Competence items asking learners to select specific therapies for patients with frequent symptoms in spite of currently being treated for asthma, learners struggled at Post-Test to correctly identify the appropriate agent.

### Classification of interleukin cytokines

On a Knowledge item asking learners to identify key Type 2 cytokines, Post-Test scores were low in spite of substantial gains.

Sanofi US and Regeneron Pharmaceuticals  
IME-2018-13285

## Learning Domain Analysis



- ❖ Learners demonstrated strong and significant improvements from Pre- to Post-Test in Knowledge and Competence
- ❖ A moderate score (3.6) was measured in learners' reported propensity to assess patients who have uncontrolled asthma for environmental triggers, inhaler technique, and comorbidities



# Curriculum Patient Impact

In the evaluation, learners (N = 383) were asked to report how many patients with asthma they see in any clinical setting per week by selecting a range. The resulting distribution of learner responses was then extrapolated to reflect the total number of learners who have attended the onsite and online meetings.

The findings reveal that this education has the potential to impact

**273,529**

patients with asthma on an annual basis.

4,109–5269 patients with asthma on a weekly basis

4,109 – 5,269



## Course Director

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### **Fernando Martinez, MD, MS**

Professor of Medicine  
Weill Cornell Medical College  
New York-Presbyterian Hospital/Weill  
Cornell Medical Center,  
New York, NY

## Activity Planning Committee

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## Faculty

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### **Sandhya Khurana, MD**

Associate Professor, Pulmonary and  
Critical Care Medicine  
Co-Director, Mary Parkes Center for  
Asthma, Allergy & Pulmonary Care  
University of Rochester School of Medicine  
Rochester, NY





# NACE *Conversations* in Pulmonology 2019

## Commercial Support

The NACE 2<sup>nd</sup> Annual Conversations in Pulmonology of 2019 CME activity was supported through educational grants or donations from the following companies:

- ❖ Boehringer Ingelheim Pharmaceuticals, Inc.
- ❖ Shire
- ❖ Sanofi Genzyme and Regeneron Pharmaceuticals
- ❖ Mallinckrodt Pharmaceuticals, LLC



# Overview



## Learning Objectives

- ❖ Describe the current concepts in the pathophysiology of asthma and type 2 inflammation, and the implications of biologic therapies in the era of precision medicine
- ❖ Discuss the clinical assessment of asthma control and risk factors for poor asthma outcomes
- ❖ Individualize the treatment approach for patients with moderate to severe asthma while recognizing appropriate candidates for biologicals and other advanced therapies
- ❖ Recognize the impact of comorbid conditions on asthma control and evidence - based approaches to their treatment



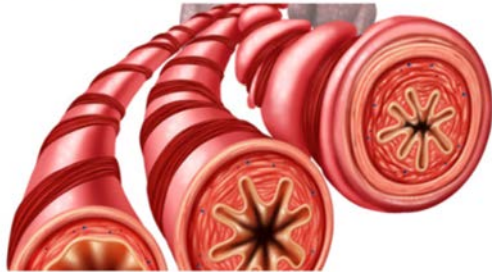
## One Live Virtual CME Symposium



## Enduring CME Symposium Webcast

<https://www.naceonline.com/courses/the-role-of-biologic-therapy-in-severe-asthma-a-shifting-treatment-paradigm>

### The Role of Biologic Therapy in Severe Asthma: A Shifting Treatment Paradigm



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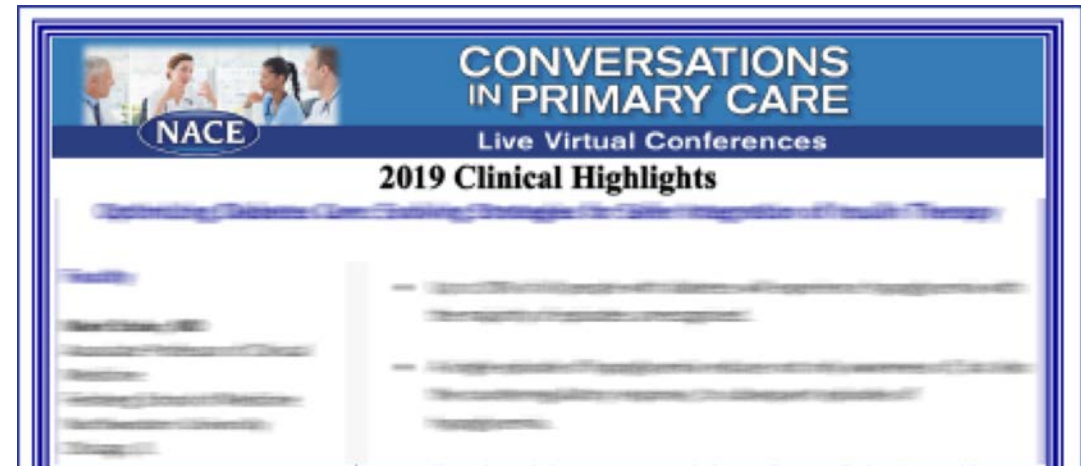
Speaker



Sandhya Khurana, MD  
 Associate Professor, Pulmonary and Critical Care Medicine  
 Co-Director, Mary Parkes Center for Asthma, Allergy & Pulmonary Care  
 University of Rochester School of Medicine  
 Rochester, NY

## Clinical Highlights eMonograph

eMonograph, containing key teaching points from the CME activity, was distributed 1 week after the meeting to all attendees.





# Outcomes Methodology

Learning outcomes were measured using matched Pre-Test and Post-Test scores for Knowledge, Performance, Confidence, and practice strategy and across all of the curriculum's Learning Objectives.

Outcomes Metric	Definition	Application
<b>Percentage change</b>	This is how the score changes resulting from the education are measured. The change is analyzed as a relative percentage difference by taking into account the magnitude of the Pre-Test average.	Differences between Pre-Test, Post-Test, and PCA score averages
<b>P value (p)</b>	This is the measure of the statistical significance of a difference in scores. It is calculated using dependent or independent samples t-tests to assess the difference between scores, taking into account sample size and score dispersion. Differences are considered significant for when $p \leq .05$ .	Significance of differences between Pre-Test, Post-Test, and PCA scores and among cohorts
<b>Effect size (d)</b>	This is a measure of the strength/magnitude of the change in scores (irrespective of sample size). It is calculated using Cohen's d formula, with the most common ranges of d from 0-1: $d < .2$ is a small effect, $d = .2-.8$ is a medium effect, and $d > .8$ is a large effect.	Differences between Pre-Test and Post-Test score averages
<b>Power</b>	This is the probability (from 0 to 1) that the "null hypothesis" (no change) will be appropriately rejected. It is the probability of detecting a difference (not seeing a false negative) when there is an effect that is dependent on the significance (p), effect size (d), and sample size (N).	Differences between Pre-Test and Post-Test score averages
<b>Percentage non-overlap</b>	This is the percentage of data points at the end of an intervention that surpass the highest scores prior to the intervention. In this report, it will reflect the percentage of learners at Post-Test who exceed the highest Pre-Test scores.	Differences between Pre-Test and Post-Test score averages

# Participation



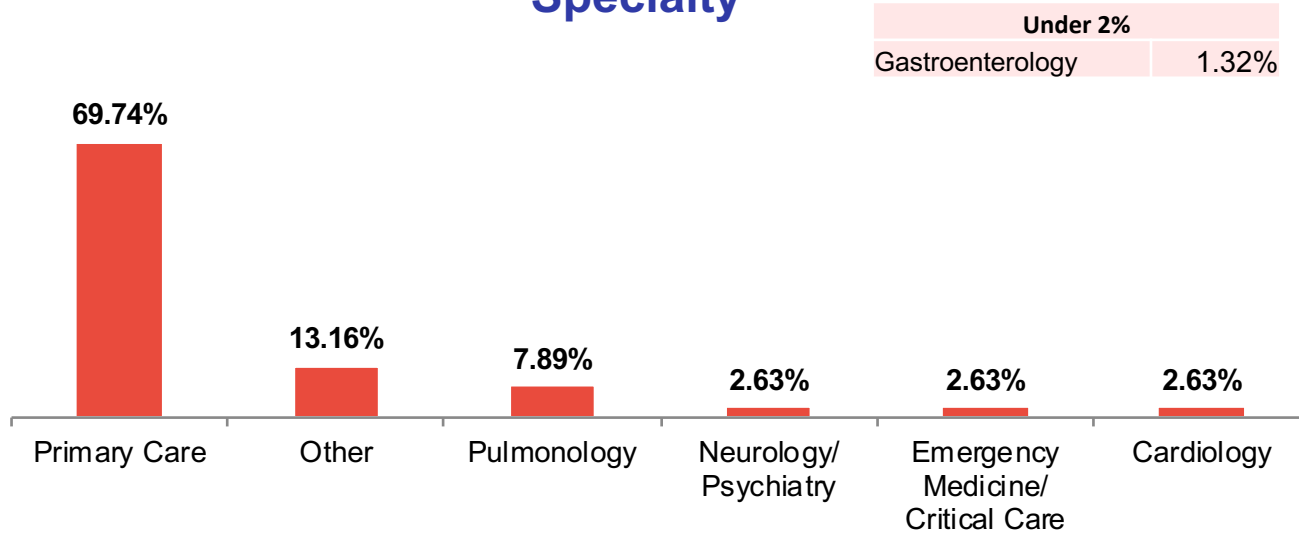
**468**  
Total Attendees



**1 Activity**

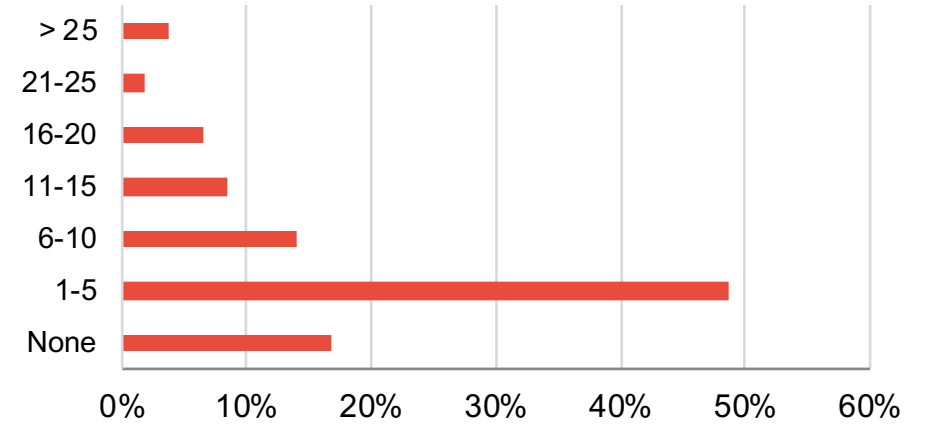
# Level 1: Demographics and Patient Reach

## Specialty



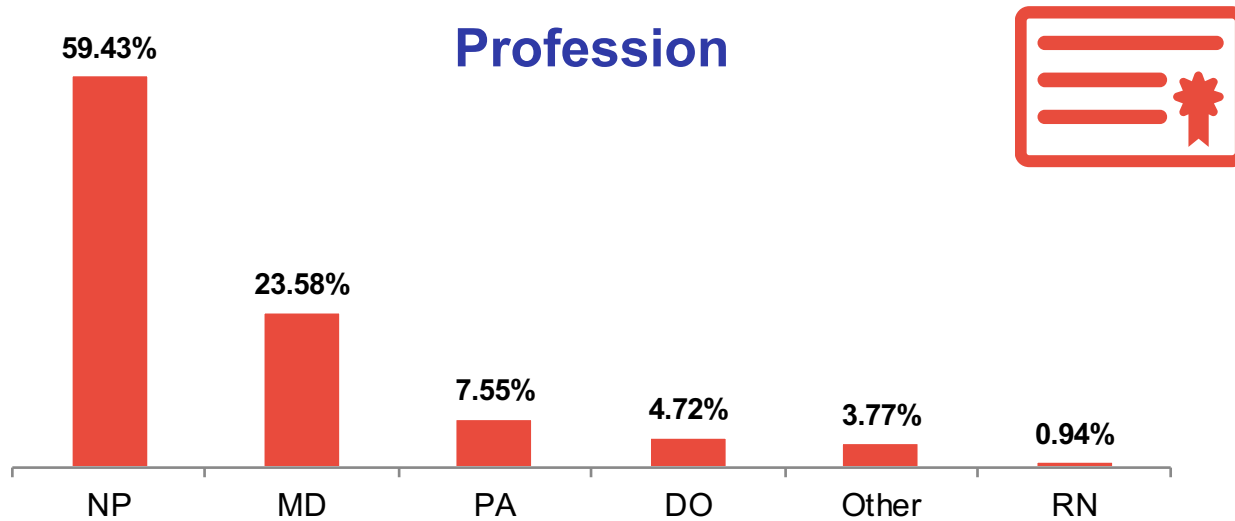
Patient Care Focus: 92%

## Patients with asthma seen each week, in any clinical setting:

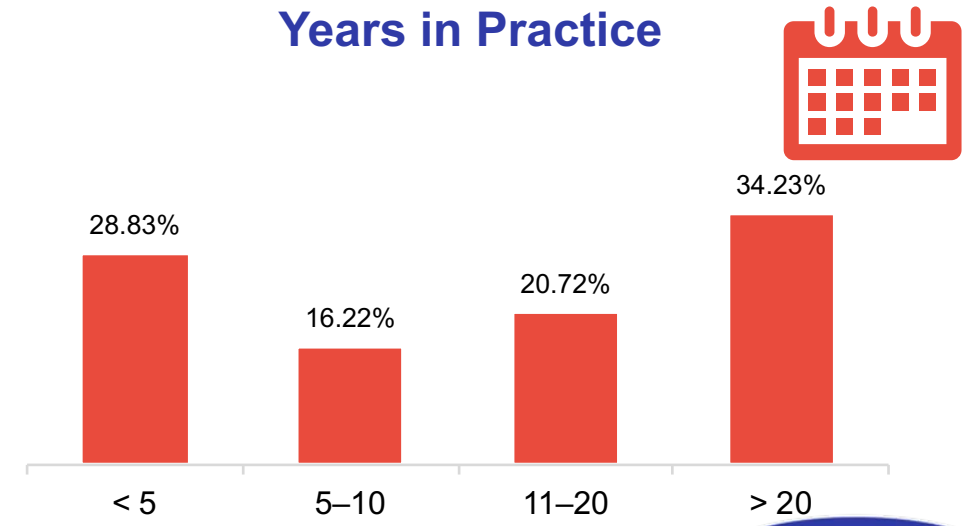


Average number of patients with asthma seen each week per clinician: 9

## Profession



## Years in Practice

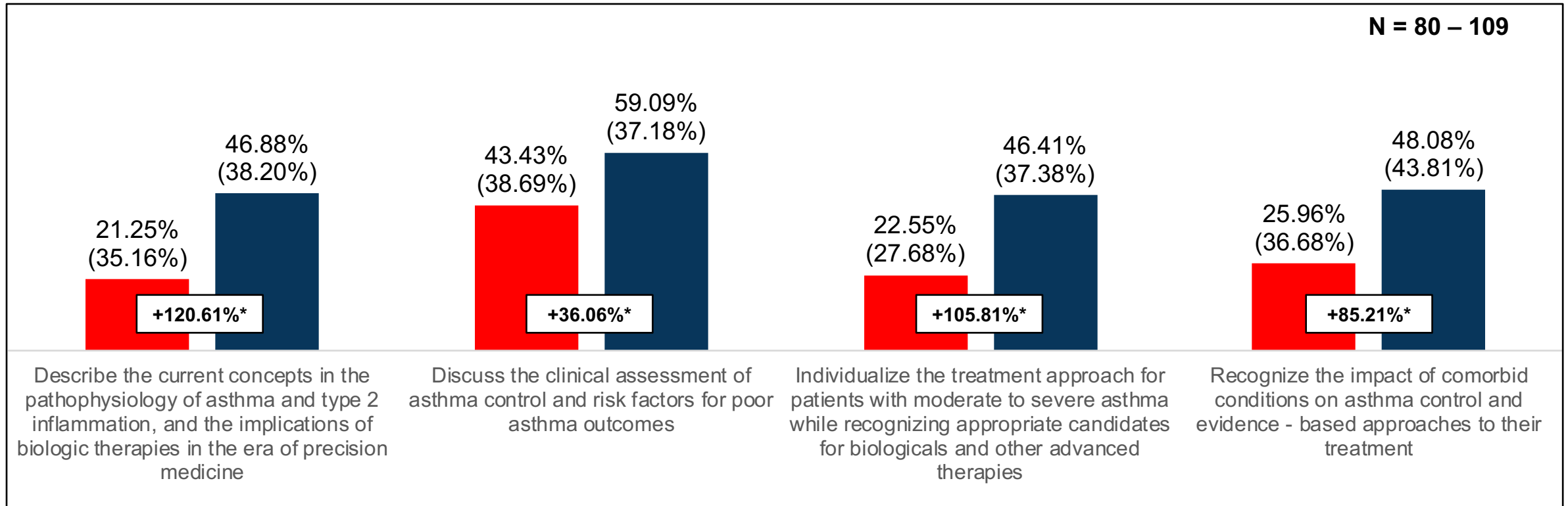




**Level 2-5:  
Outcomes Metrics**

# Learning Objective Analysis

Pre-Test  
Post-Test



- ❖ Substantial and significant improvements were measured across all curriculum Learning Objectives, from Pre- to Post-Test
- ❖ Pre- and Post-Test scores were low for all Learning Objectives, due to uniformly low scores on scored Knowledge and Competence questions
  - ❖ The highest scoring item, about use of targeted therapies, had an average Post-Test score of 73%

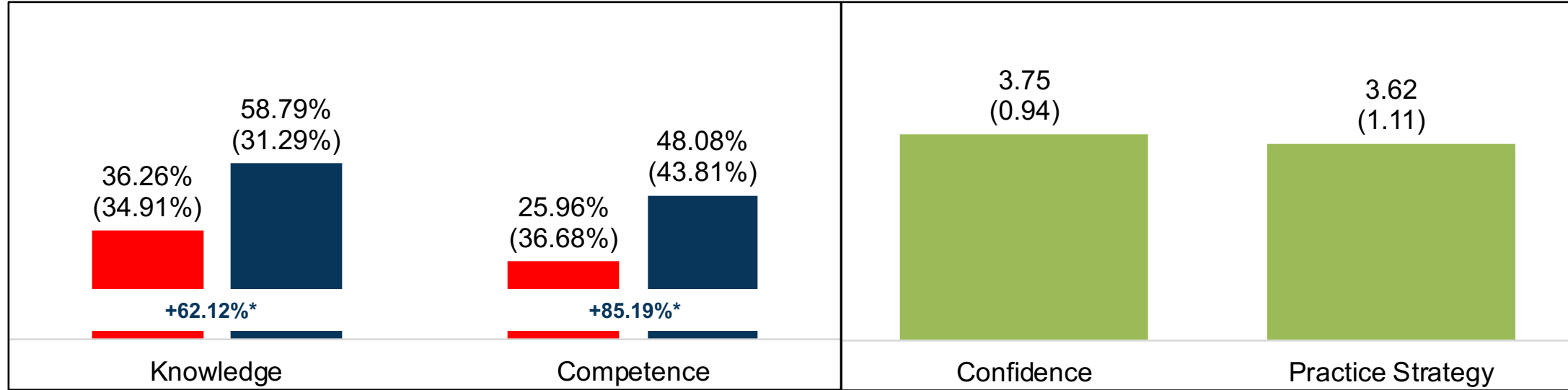
Note: data are matched.

\* indicates significance,  $p < 0.05$ .

# Learning Domain Analysis

Pre-Test Post-Test PCA

(N = 91–116)

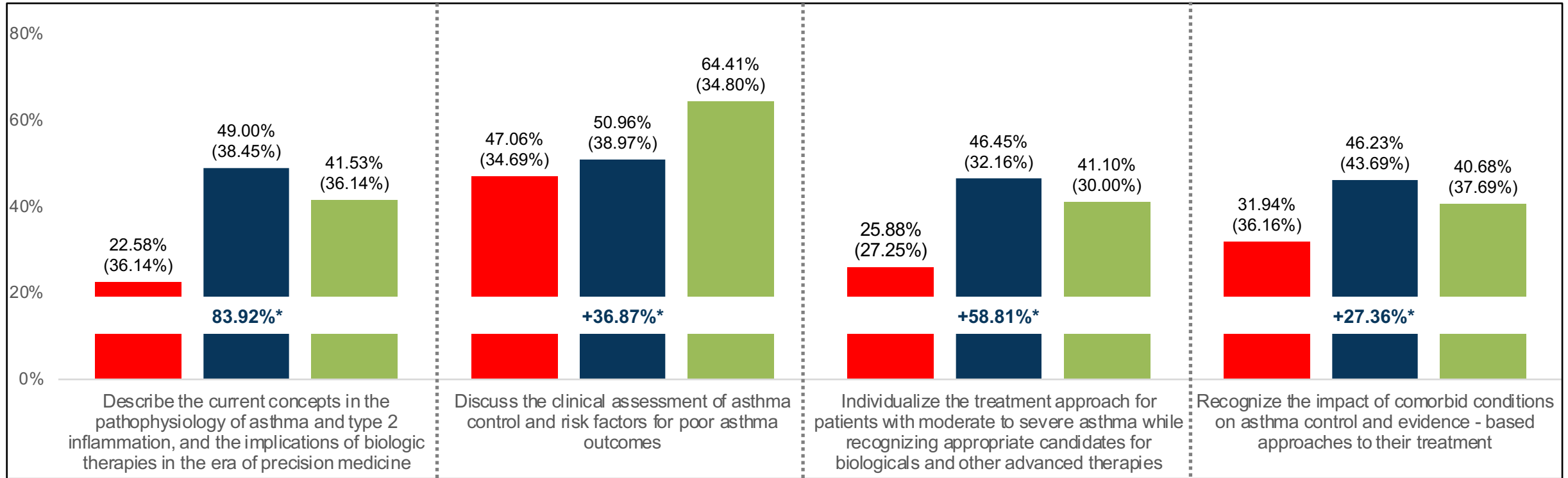


- ❖ Learners demonstrated strong and significant improvements from Pre- to Post-Test in Knowledge and Competence
  - ❖ In spite of these gains, Post-Test scores in both Knowledge and Competence remained low
- ❖ Though Post-Test scores in Knowledge and Competence were low, over half of learners gave a 4 or 5 rating to the improvement in their confidence in their ability to integrate biologic therapy for patients with severe asthma
- ❖ A moderate score (3.6) was measured in learners' reported propensity to assess patients who have uncontrolled asthma for environmental triggers, inhaler technique, and comorbidities

# Learning Objectives Retention Analysis – 4 weeks

Pre-Test Post-Test PCA

(N = 59–199)



- ❖ Substantial and significant gains were retained all of the four curriculum Learning Objectives
- ❖ On three of the four Learning Objectives, scores decreased mildly from Post-Test to follow-up
  - ❖ Learners' understanding of assessment of asthma control and risk factors for poor outcomes increased substantially between the Post-Test and follow-up measurements, highlighting ongoing improvements in this area

Note: data is matched; learners with a score for the given domain on both the Pre-Test and PCA are included

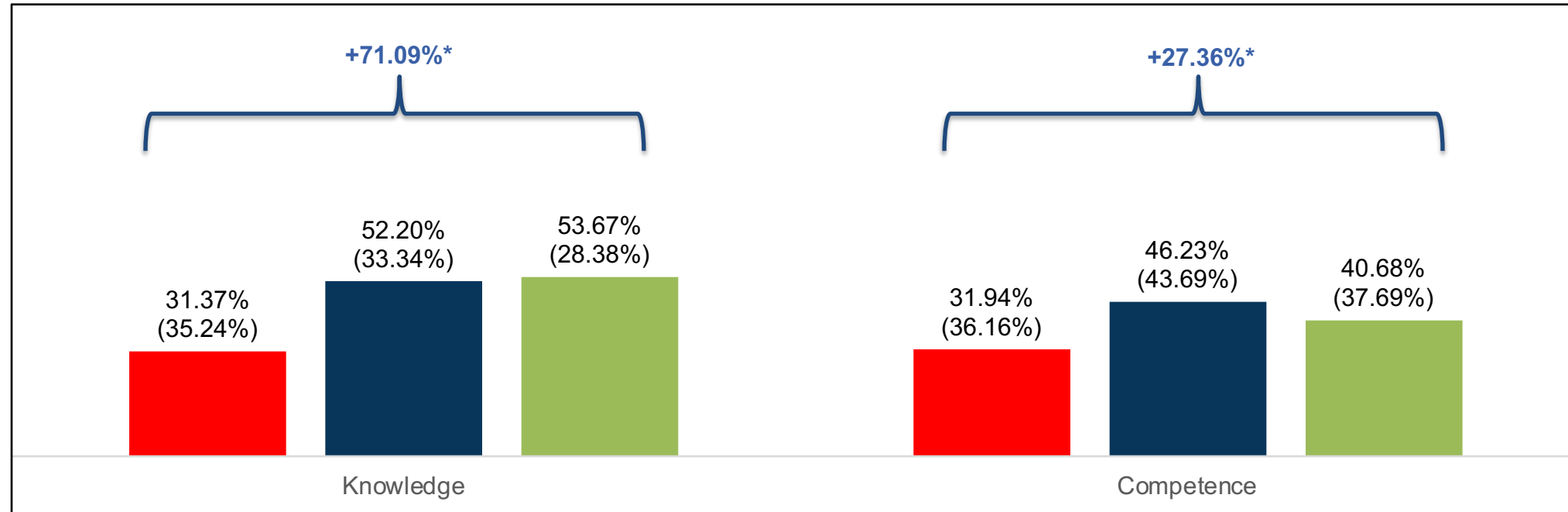
\*significant at the  $p \leq 0.05$  level



# Learning Domain Retention Analysis – 4 weeks

Pre-Test Post-Test PCA

(N = 116 – 199)



At follow-up:

- ❖ In addition to collecting Confidence and Practice data for the curriculum, the Post Curriculum Assessment (PCA) included questions from the Knowledge and Competence domains
- ❖ A statistically significant net gain was measured from Pre-Test to the Post Curriculum Assessment (PCA) in both Knowledge (71%) and Competence (27%)
- ❖ In both Competence, some decrease in score was measured between Post-Test and PCA, reflecting a need for further reinforcement of case-based content

*Note: data is matched; learners with a score for the given domain on both the Pre-Test and PCA are included*

*\*significant at the  $p \leq 0.05$  level*



# Cohort Comparison by Profession: Learning Objectives

Learning Objective	Nurse Practitioners				Physicians			
	N	Pre-Test	Post-Test	% Change	N	Pre-Test	Post-Test	% Change
Describe the current concepts in the pathophysiology of asthma and type 2 inflammation, and the implications of biologic therapies in the era of precision medicine	29	13.79% (25.92%)	34.48% (32.44%)	+150.04%*	14	35.71% (44.03%)	64.29% (39.77%)	+80.03%*
Discuss the clinical assessment of asthma control and risk factors for poor asthma outcomes	36	44.44% (42.13%)	59.72% (38.76%)	+34.38%*	16	46.88% (37.37%)	59.38% (36.31%)	+26.66%
Individualize the treatment approach for patients with moderate to severe asthma while recognizing appropriate candidates for biologicals and other advanced therapies	39	18.16% (24.74%)	46.79% (37.68%)	+157.65%*	18	31.94% (34.83%)	57.87% (34.41%)	+81.18%*
Recognize the impact of comorbid conditions on asthma control and evidence - based approaches to their treatment	37	22.97% (34.08%)	51.35% (44.25%)	+123.55%*	18	25.00% (38.19%)	47.22% (42.40%)	+88.88%

- ❖ Substantial improvements across all Learning Objectives were measured for both nurse practitioners and physicians
- ❖ These gains were greater for nurse practitioners, though physicians had higher or similar Post-Test scores
- ❖ These results should be interpreted with caution due to the small sample size

# Cohort Comparison by Profession: Learning Domains

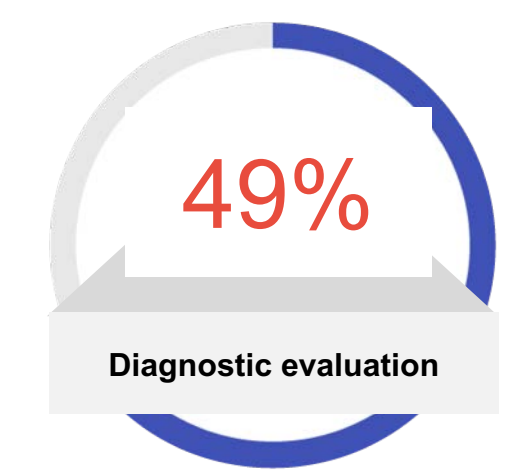
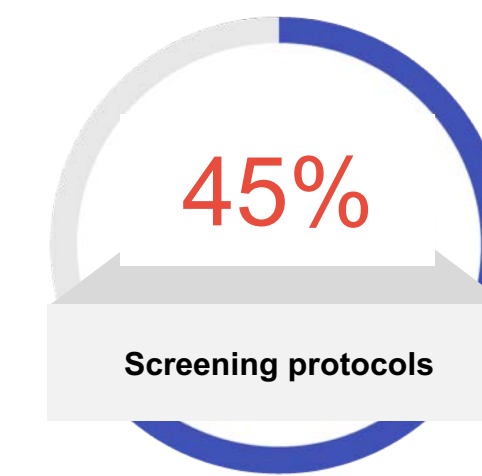
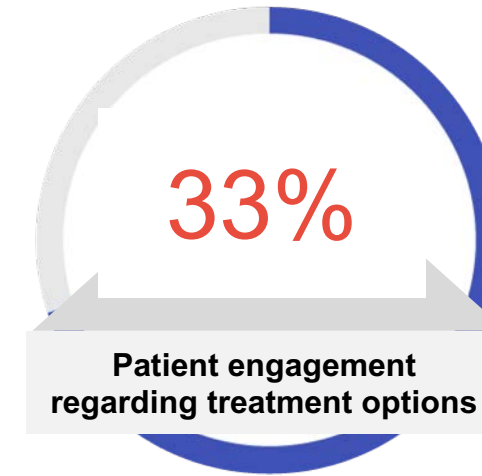
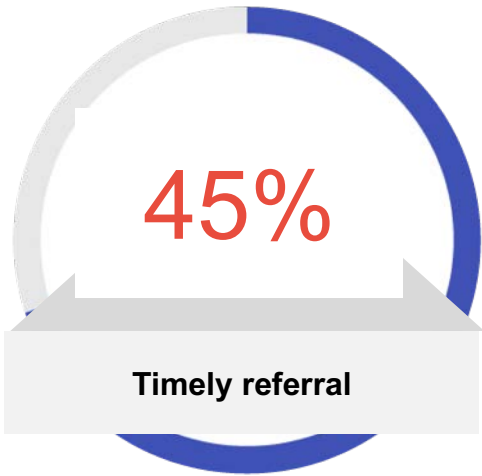
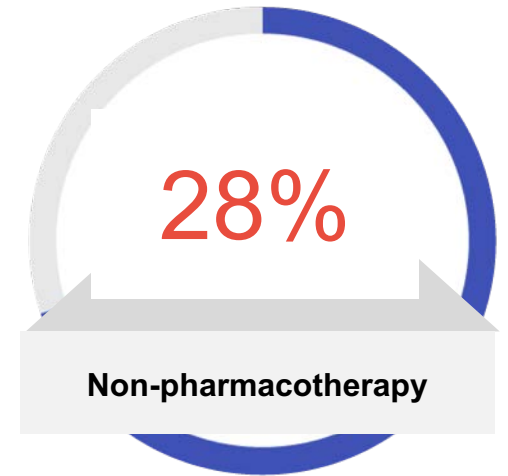
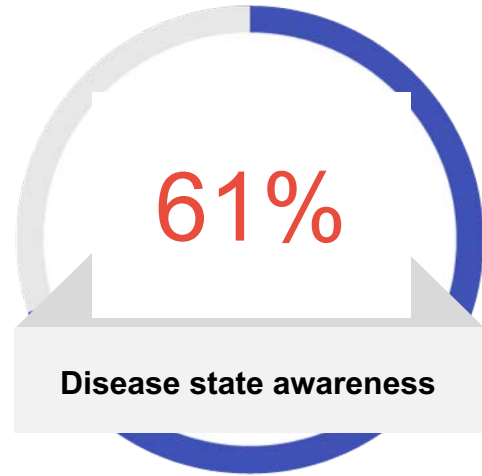
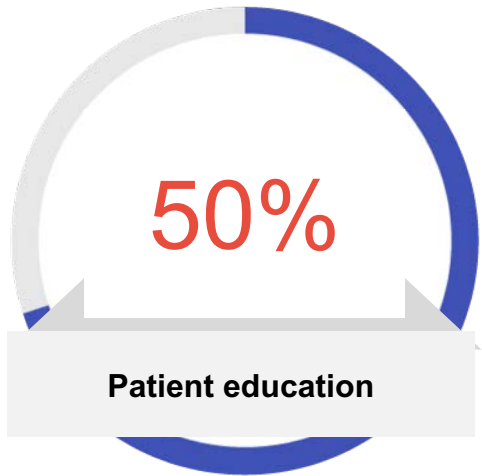
Learning Domain	Nurse Practitioners				Physicians			
	N	Pre-Test	Post-Test	% Change	N	Pre-Test	Post-Test	% Change
Knowledge	34	32.84% (33.45%)	48.53% (31.41%)	+47.78%*	15	52.22% (35.94%)	65.56% (34.68%)	+25.55%
Competence	37	22.97% (34.08%)	51.35% (44.25%)	+123.55%*	18	25.00% (38.19%)	47.22% (42.40%)	+88.88%*

- ❖ Substantial improvements in both Knowledge and Competence were measured for both nurse practitioners and physicians
- ❖ These gains were greater for nurse practitioners, though physicians had higher or similar Post-Test scores
- ❖ These results should be interpreted with caution due to the small sample size

(4-week Post Assessment)

**Please select the specific areas of *skills, or practice behaviors*, you have improved regarding the treatment of patients with asthma since this CME activity. (Select all that apply.)**

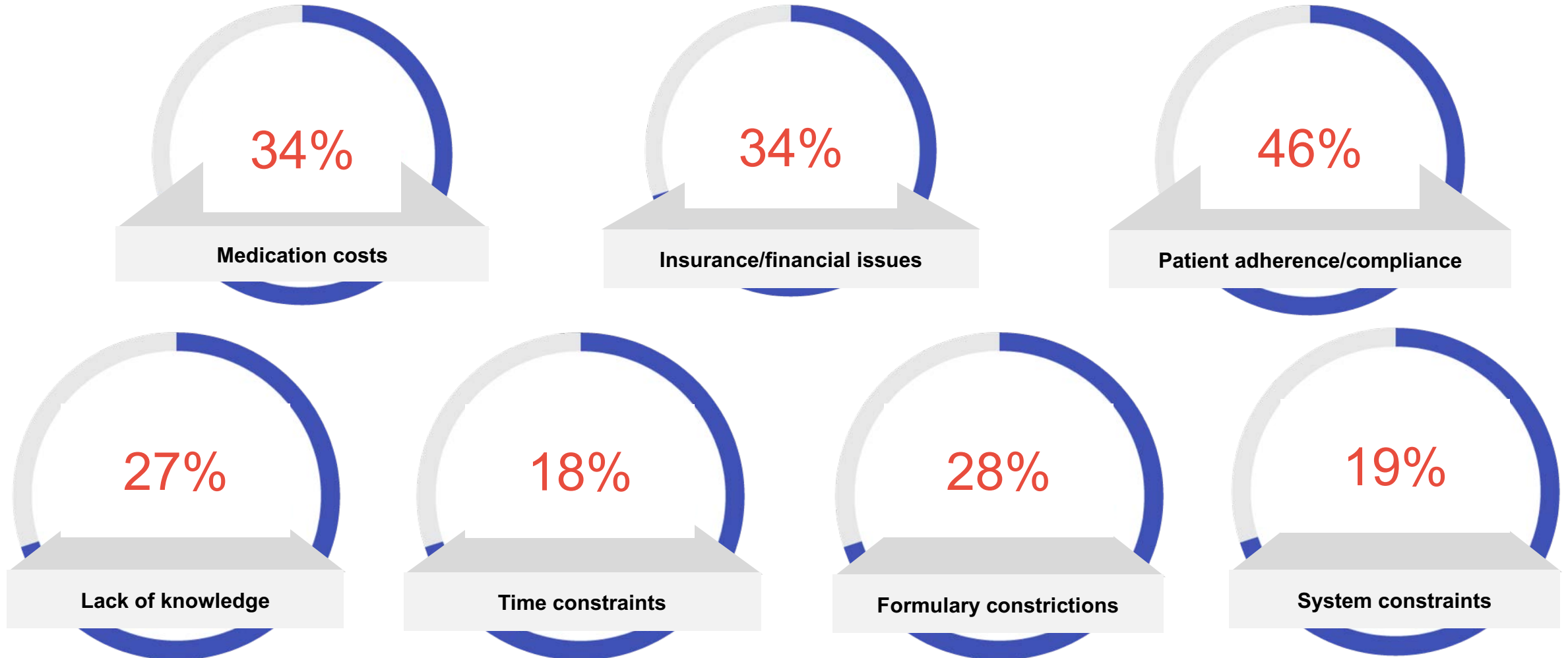
N=116



(4-week Post Assessment)

# What specific *barriers* have you encountered that may have prevented you from successfully implementing strategies for patients with asthma since this CME activity? (Select all that apply.)

N=116



## Identified Learning Gap, 1 of 3:

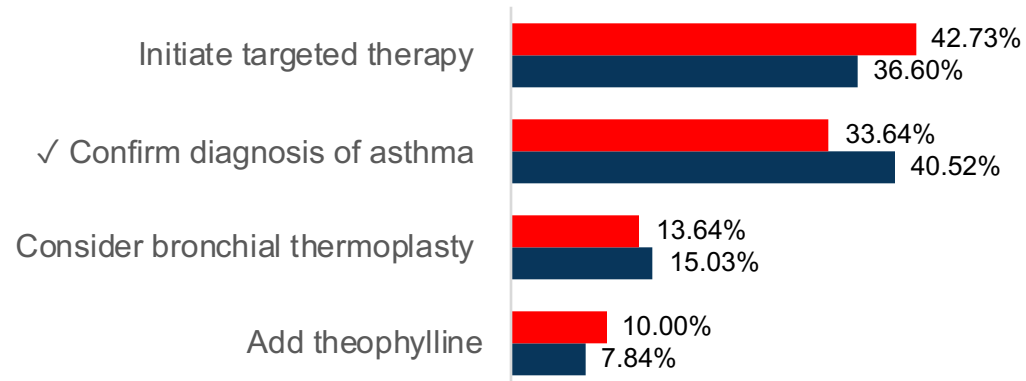
### *Importance of confirming diagnosis for patients with apparent uncontrolled asthma*

On a Competence item asking learners to identify the appropriate next step for a patient with a long history of diagnosed asthma and daily symptoms, learners struggled at Post-Test to correctly identify the need to confirm the asthma diagnosis.

**Competence: A 59-year-old obese woman with 20-year history of physician diagnosed asthma presents with daily asthma symptoms, nighttime awakenings 2-3 nights per week, and frequent use of a rescue inhaler. She reports difficulty walking uphill or a flight of stairs. Current medications include high-dose ICS/LABA and LAMA. Which of the following would be the appropriate next step?**

#### Results:

- At Post-Test, 41% of learners correctly answered: "Confirm diagnosis of asthma"



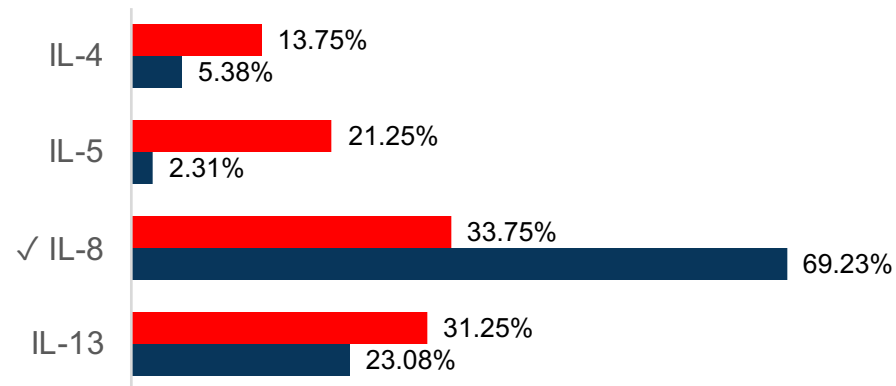
## Identified Learning Gap, 2 of 3: *Classification of interleukin cytokines*

On a Knowledge item asking learners to identify key Type 2 cytokines, Post-Test scores were low in spite of substantial gains.

**Knowledge:** All of the following are key Type 2 cytokines except:

### Results:

- At Post-Test, 69% of learners correctly answered: "IL-8"



# Identified Learning Gap, 3 of 3:

## *Treatment selection for asthma patients unmanaged by current therapies*

On Knowledge and Competence items asking learners to select specific therapies for patients with frequent symptoms in spite of currently being treated for asthma, learners struggled at Post-Test to correctly identify the appropriate agent.

**Knowledge: Which of the following add-on therapies would be most appropriate for a patient who has severe uncontrolled asthma despite GINA step 4 therapy and low levels of Type 2 inflammation?**

### **Results:**

- At Post-Test, only 29% of learners correctly answered: “Bronchial thermoplasty”

**Competence: 44-y/o man with history of asthma since childhood presents with frequent asthma symptoms despite treatment with high-dose ICS/LABA plus LAMA, and prednisone 10 mg/day. He has required two hospitalizations in the last one year for acute asthma. Comorbidities include atopic dermatitis, poorly controlled with topical agents. Spirometry reveals moderate airflow obstruction with bronchodilator reversibility. Patient demonstrates good inhaler technique and confirms regular use of medications. Serum IgE 20 kU/l. Negative allergen skin testing. Blood eosinophils 450 cells per mcL. Which of the following agents might be most appropriate at this time?**

### **Results:**

- At Post-Test, only 42% of learners correctly answered: “Dupilumab”

# Overall Educational Impact

- ❖ Significant and substantial improvements (of 62% and 85%) were seen in both learner Knowledge and Competence
  - Post-Test scores of 59% and 48% were measured in Knowledge and Competence, following low (36% and 26%) Pre-Test scores
  - Final scores on Confidence and practice strategy questions were moderate (3.75 and 3.62), and collected in the Post Curriculum Assessment (PCA)
- ❖ Substantial and significant improvements ranging from 36% to 121% were measured across all four Learning Objectives, from Pre-Test to Post-Test, but remained low at Post-Test
- ❖ The analysis of the Knowledge and Competence domains identified three **persistent learning gaps related to the importance of confirming the diagnosis of asthma for patients with apparent uncontrolled asthma, classification of interleukin cytokines, and treatment selection for asthma patients unmanaged by current therapies**
  - Pre- and Post-Test scores were low on a Competence item asking learners to identify which the appropriate next step for a patient with a long history of diagnosed asthma and daily symptoms
  - Scores were also low on a Knowledge item asking learners to identify key Type 2 cytokines
  - A knowledge and a competence question both asked learners to select specific therapies for frequent asthma symptoms in spite of current treatments; scores were low for both



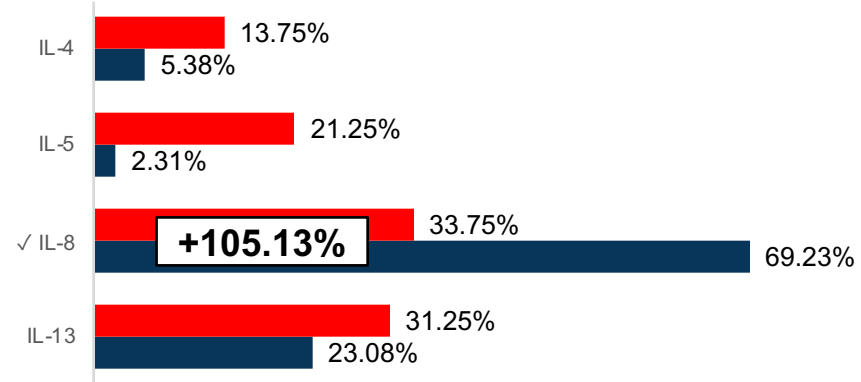
# Appendix

# Knowledge Items

Pre-Test  
Post-Test

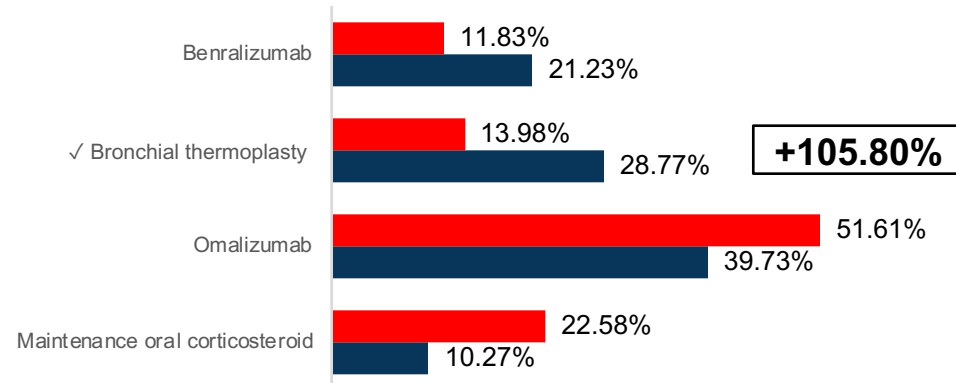
All of the following are key Type 2 cytokines except:

N = 80 – 130



Which of the following add-on therapies would be most appropriate for a patient who has severe uncontrolled asthma despite GINA step 4 therapy and low levels of Type 2 inflammation?

N = 93 – 146

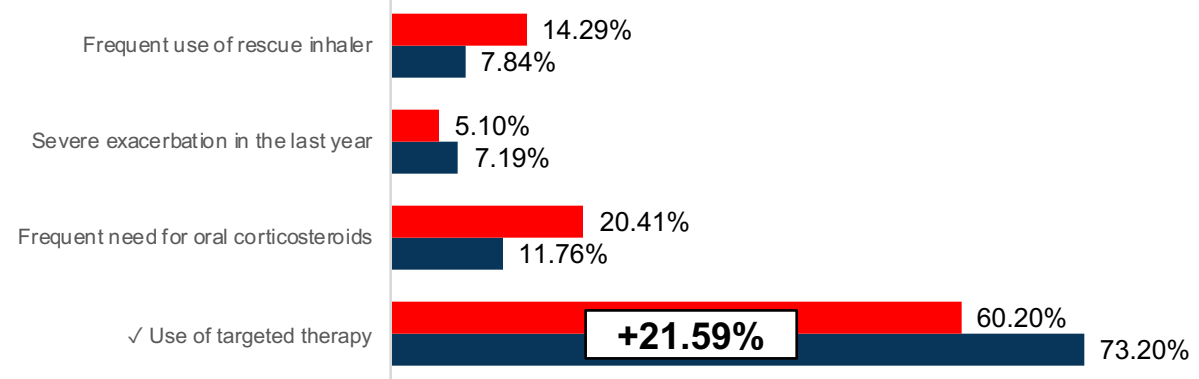


# Knowledge Items

Pre-Test  
Post-Test

All of the following are associated with increased future risk for poor asthma outcomes, EXCEPT:

N = 98 – 153

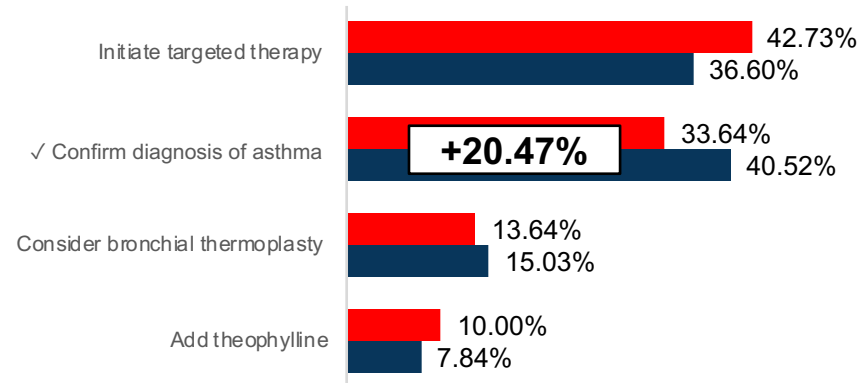


# Competence Items

Pre-Test  
Post-Test

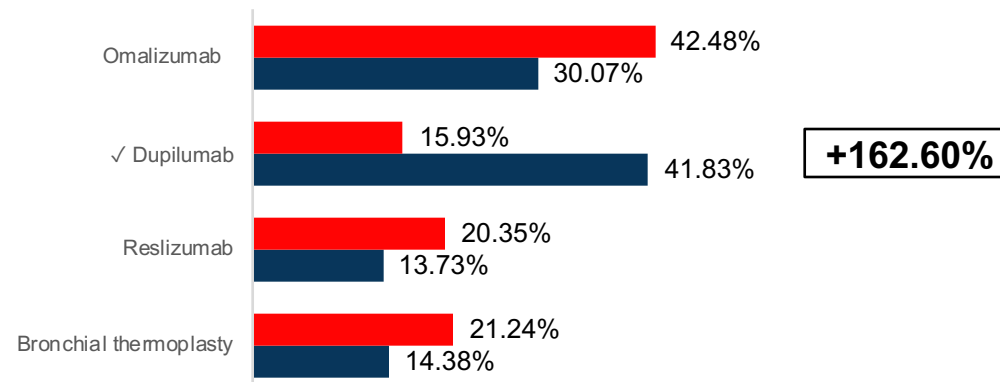
A 59-year-old obese woman with 20-year history of physician diagnosed asthma presents with daily asthma symptoms, nighttime awakenings 2-3 nights per week, and frequent use of a rescue inhaler. She reports difficulty walking uphill or a flight of stairs. Current medications include high-dose ICS/LABA and LAMA. Which of the following would be the appropriate next step?

N = 110 – 153



44-y/o man with history of asthma since childhood presents with frequent asthma symptoms despite treatment with high-dose ICS/LABA plus LAMA, and prednisone 10 mg/day. He has required two hospitalizations in the last one year for acute asthma. Comorbidities include atopic dermatitis, poorly controlled with topical agents. Spirometry reveals moderate airflow obstruction with bronchodilator reversibility. Patient demonstrates good inhaler technique and confirms regular use of medications. Serum IgE 20 kU/l. Negative allergen skin testing. Blood eosinophils 450 cells per mL. Which of the following agents might be most appropriate at this time?

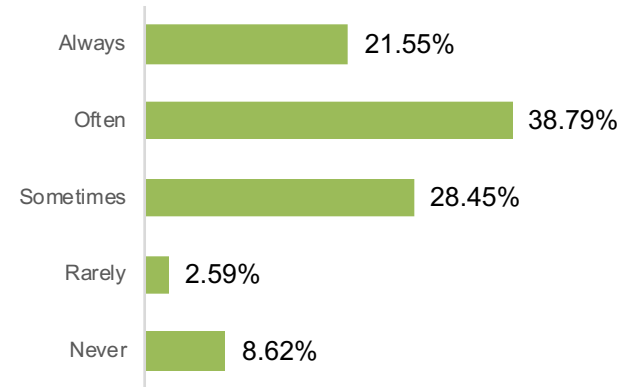
N = 113 – 153



## Practice Strategy Item (given at 4 week follow-up)

Please rate your level of agreement with the following statement, since attending the Conversations program: I more often assess patients who have uncontrolled asthma for environmental triggers, inhaler technique, and comorbidities

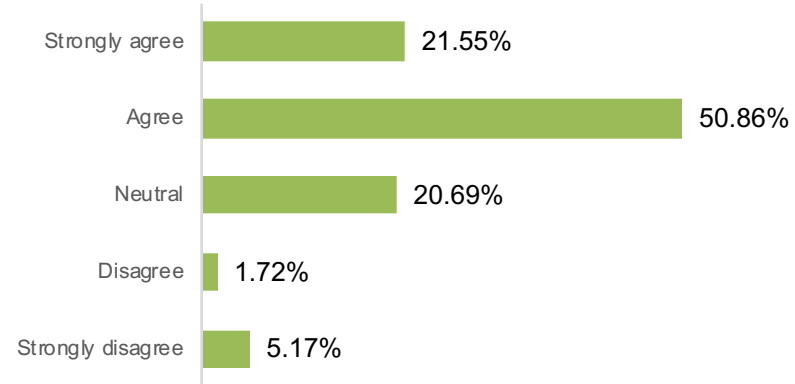
N = 116



# Confidence Items (given at 4 week follow-up)

Please rate your level of agreement with the following statement: I am much more confident in my ability to recognize patients who meet the diagnostic criteria for severe asthma

N = 116



Please rate your level of agreement with the following statement: I am much more confident in how to integrate biologic therapy into the care of patients with severe asthma

N = 116

