



Emerging Challenges in Primary Care

18th Annual Conference Series - 2019

Pushing the Threshold of Lipid Lowering: Incorporating the Evolving Database into Practice



Final Live Outcomes Report

Sanofi-Regeneron • IME-2019-14260

April 15, 2020



Participation

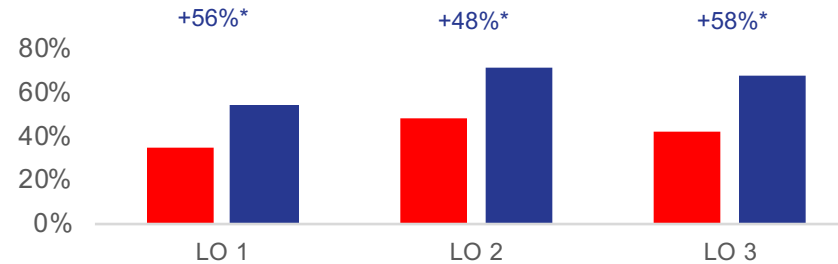


This education has the potential to impact **1,378,006** patients with hyperlipidemia on an annual basis.

23,850–29,150 Patients Weekly

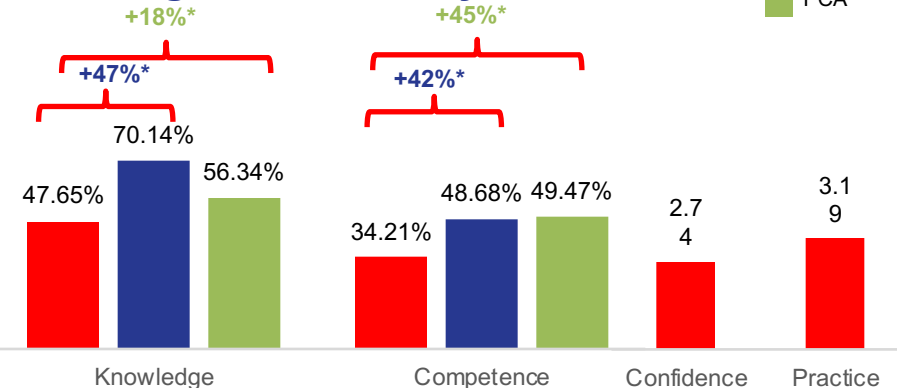
2019 Meeting/Simulcast	Date	Attendees
Virtual Symposium	9/21/19	469
Uniondale, NY	10/12/19	243
San Mateo, CA	10/19/19	86
Houston, TX	10/26/19	180
San Diego, CA	10/29/19	138
San Diego Simulcast	10/29/19	597
Total		1,713

Learning Gains Across Objectives



- ❖ **LO 1:** Discuss the latest 2018 ACC/AHA Multi-society Guideline on the Management of Blood Cholesterol to reduce the risk of cardiovascular disease
- ❖ **LO 2:** Incorporate current data surrounding non-statin therapy into secondary prevention treatment strategies for patients with the highest cardiovascular risk
- ❖ **LO 3:** Overcome barriers to access for PCSK9 monoclonal antibody therapy

Learning Domain Analysis



- ❖ Statistically significant net gains were measured from Pre-Test to PCA in both Knowledge and Competence
- ❖ In Competence, ongoing improvements in score were measured from Post-Test to PCA, while some score slippage was seen in Knowledge
- ❖ Learner ratings in Confidence and practice strategy, given only at Pre-Test, were moderate, reflecting learner awareness of their Knowledge and Competence gaps in this area

Persistent Learning Gaps/Needs

Obtaining approval for PCSK9i therapy

Despite improvements in score on a Competence item asking learners what might facilitate prior approval for PCSK9i therapy for a given patient, only 64% at post test recognized the need to include appropriate records



Engaging in appropriate risk discussion with patients

On a Competence item where learners were asked whether to consider statin therapies, only 34% of learners at post test the need to discuss the risk of moderate-intensity statin therapy with a patient before initiating treatment.



Role of familial hypercholesterolemia in treatment selection

On a Knowledge item about approved indications for PCSK9i therapy, learners struggled at Post-Test. Only 61% correctly answered "familial hypercholesterolemia".



Curriculum Patient Impact

In the evaluation, learners (N = 941) were asked to report how many patients with hyperlipidemia 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

1,378,006

patients with hyperlipidemia on an annual basis.

23,850–29,150 patients on a weekly basis

23,850–
29,150

Course Directors

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Lipidology & Cardiovascular Disease Prevention
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NYU Medical School & NYU Center for CV Prevention
Director, Bellevue Hospital Lipid Clinic
Past President National Lipid Association
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Commercial Support

The Emerging Challenges in Primary Care: 2019 series of CME activities were supported through educational grants or donations from the following companies:

- ❖ Amarin Pharma Inc.
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- ❖ Ferring Pharmaceuticals, Inc.
- ❖ Gilead Sciences, Inc
- ❖ Grifols
- ❖ Novo Nordisk, Inc.
- ❖ Sanofi US and Regeneron Pharmaceuticals
- ❖ Shire

Overview

Learning Objectives

- ❖ Discuss the latest 2018 ACC/AHA Multi-society Guideline on the Management of Blood Cholesterol to reduce the risk of cardiovascular disease
- ❖ Incorporate current data surrounding non-statin therapy into secondary prevention treatment strategies for patients with the highest cardiovascular risk
- ❖ Overcome barriers to access for PCSK9 monoclonal antibody therapy



4 Live Regional Symposia with 1 National Simulcast
October 12, 2019 – November 2, 2019



1 Live Virtual Symposium – November 30, 2019



Enduring CME Symposium Webcast

Pushing the Threshold of Lipid Lowering:
Incorporating the Evolving Database into Practice



Speaker



James Underberg, MD, MS, FACP, FACP
Lipidology & Cardiovascular Disease Prevention
Clinical Assistant Professor of Medicine
NYU Medical School & NYU Center for CV Prevention
Director, Bellevue Hospital Lipid Clinic
Past President National Lipid Association
New York, NY

Moderator



Ashlyn Smith, MMS, PA-C
Endocrinology Associates, P.A.
President, American Society of Endocrine
Physician Assistants
Adjunct Assistant Professor, Midwestern University
Scottsdale, AZ

COURSE SUMMARY

Cost: Free
Start Date: 11/30/2019
Expiration Date: 11/29/2020
Target Audience: Primary Care Providers
Format: Webcast
Estimated Time To Complete CME Activity: 1.0 hour
Credit(s): 1.0 *AMA PRA Category 1 Credit(s)*TM
1.0 AANP Contact Hour(s) which includes 0.5 pharmacology hours
Hardware/Software Requirements: Any web browser

Clinical Highlights eMonograph

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

Emerging Challenges in Primary Care

LIVE CONFERENCE SERIES

2019 Clinical Highlights

Pushing the Threshold of Lipid Lowering: Incorporating the Evolving Database into Practice

Faculty

James Underberg, MD, MS, FACP, FACP
Lipidology & Cardiovascular Disease Prevention
Clinical Assistant Professor of Medicine
NYU Medical School & NYU Center for

- Statin therapy is a cornerstone of primary and secondary prevention of cardiovascular events
- Multiple lines of evidence strongly support a causal relationship between LDL-C and atherosclerotic cardiovascular disease (ASCVD)
- Despite widespread statin therapy, many patients with ASCVD risk have LDL-C levels above recommended targets
- The 2018 Blood Cholesterol Guidelines for primary prevention recommend statin therapy based on the following risk categories:

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
Percentage change	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
P value (p)	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
Effect size (d)	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
Power	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
Percentage non-overlap	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

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San Diego Simulcast	10/29/29	597
Total		1,713



Participation



1,713*
Total Attendees



4 Cities



647*
On Site

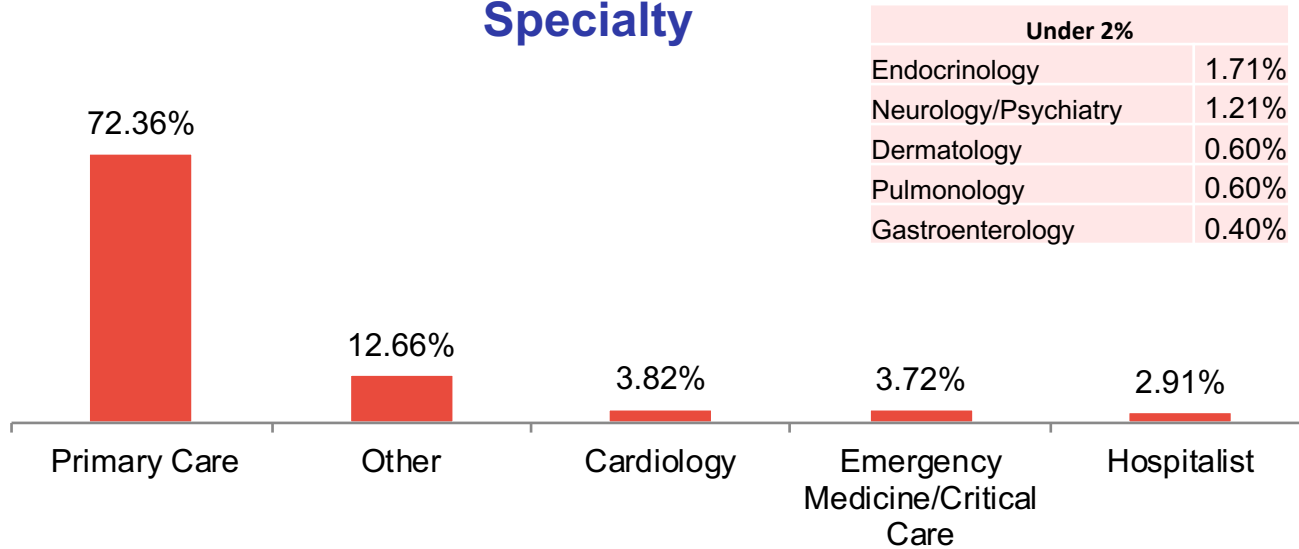


1,066*
Simulcast / Virtual
Symposium

*These numbers represent the total number of attendees, irrespective of assessment participation

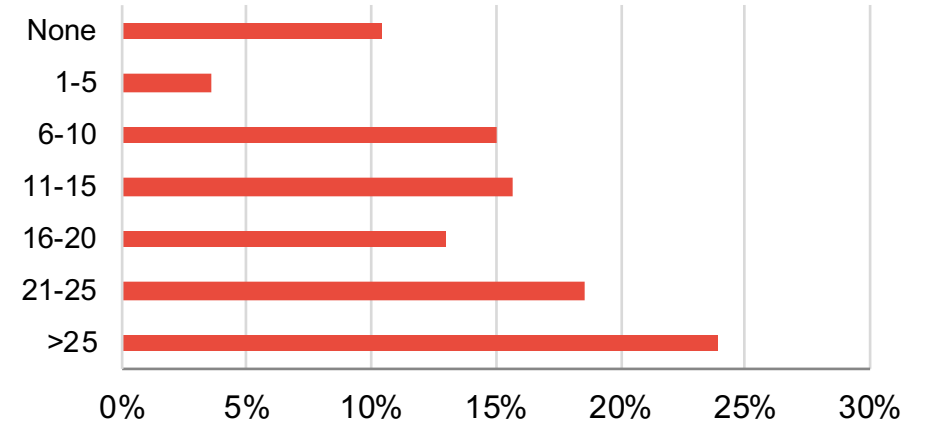
Level 1: Demographics and Patient Reach

Specialty



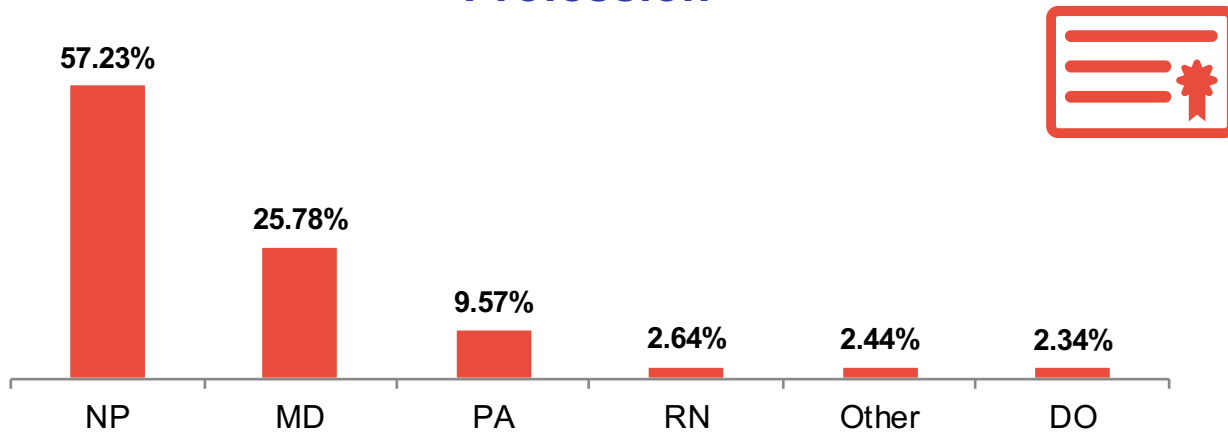
Patient Care Focus: 91%

Patients with hyperlipidemia seen each week, in any clinical setting:

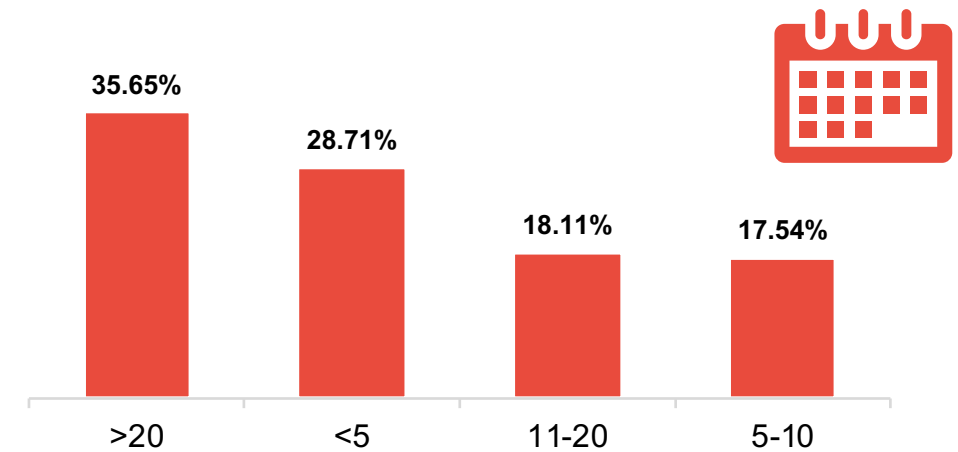


Average number of patients with hyperlipidemia seen each week per clinician: 17

Profession



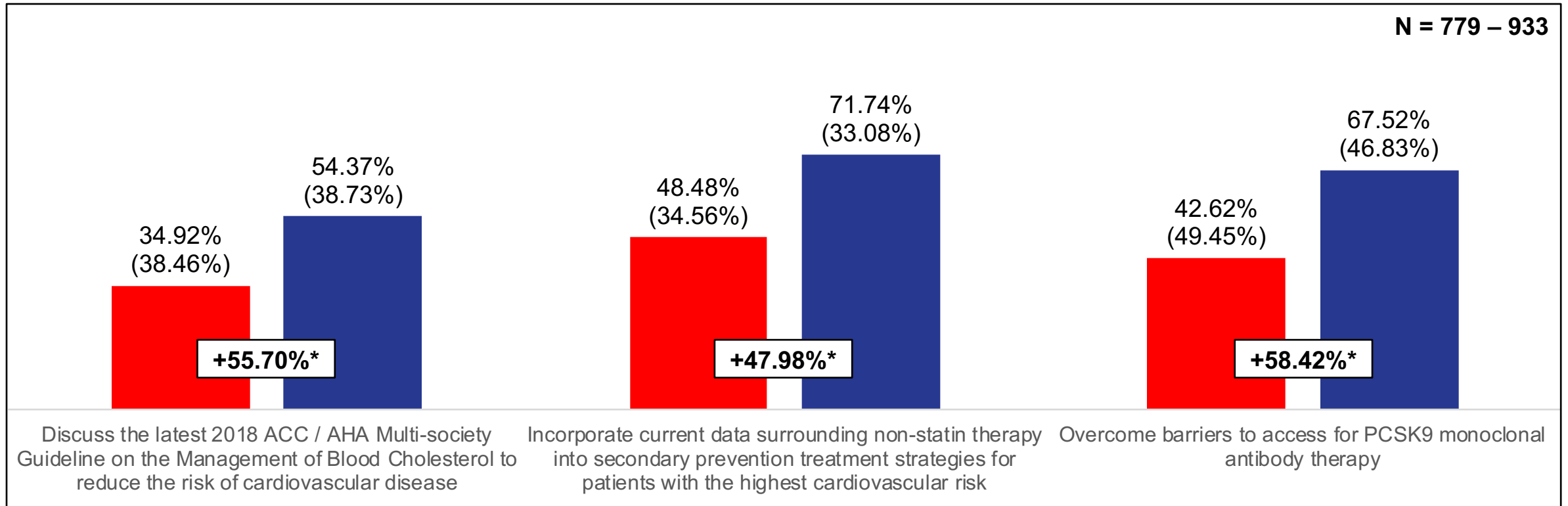
Years in Practice



Level 2-5: Outcomes Metrics

Learning Objective Analysis

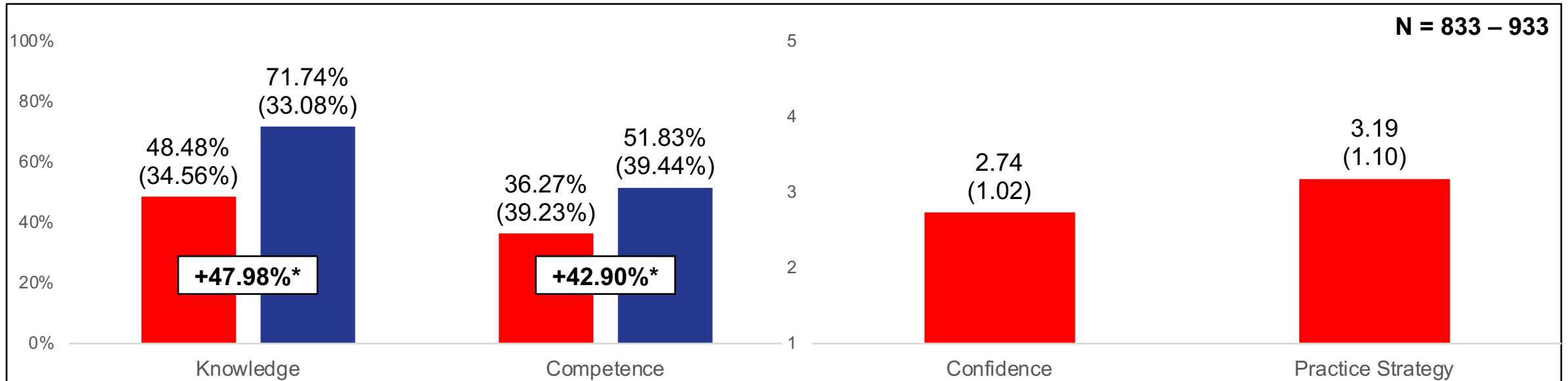
Pre-Test
Post-Test



- ❖ Learners achieved substantial and significant improvements on all three curriculum Learning Objectives, from low Pre-Test scores to moderate Post-Test scores
- ❖ The lowest Pre- and Post-Test scores (35% and 54%, respectively), were measured on the Objective related to guidelines on the management of blood cholesterol to reduce the risk of cardiovascular disease
 - ❖ Scores on this Objective were driven down by a Competence item presenting the case of a patient in need of a risk discussion regarding moderate-intensity statin therapy
- ❖ On the other two Objectives, similar scores across associated items were measured at Pre- and Post-Test

Learning Domain Analysis

Pre-Test
Post-Test



- ❖ Curriculum learners achieved substantial and significant gains in average score in Knowledge and Competence, from Pre- to Post-Test measurements
 - ❖ Low Pre- and Post-Test scores in Competence were driven by an item presenting the case of a patient in need of risk discussion regarding moderate-intensity statin therapy
 - ❖ Low to moderate Pre-Test scores (41% to 61%) and moderate Post-Test scores (69% to 73%) were measured across all three Knowledge items
- ❖ Learner ratings in Confidence and practice strategy, given at Pre-Test, were moderate, reflecting awareness of Knowledge and Competence gaps in this area

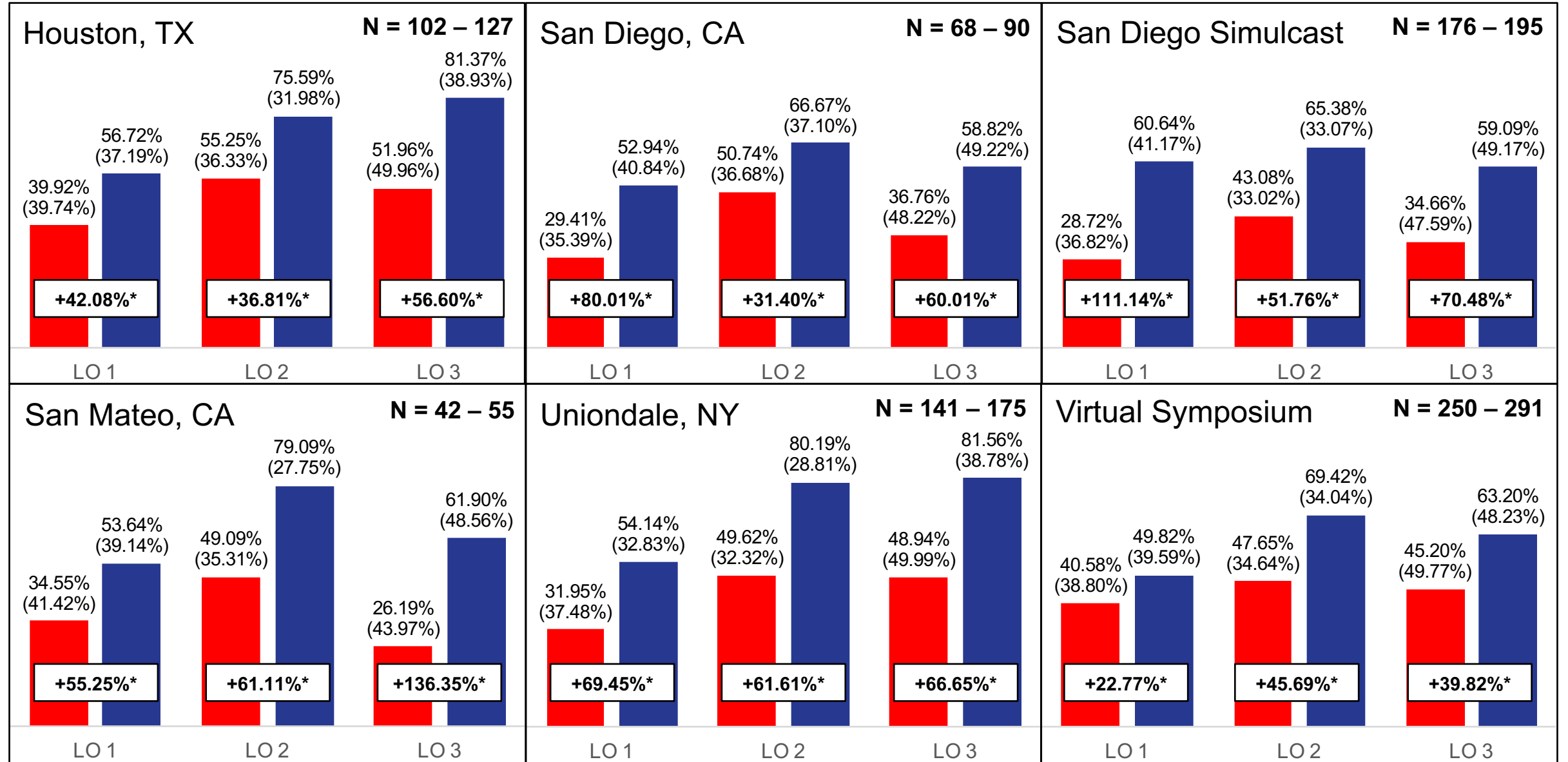
Learning Objective Analysis, Per Site

Learning Objective scores at Pre- and Post-Test were independently analyzed for each of the six sites (see next slide)

- **LO 1:** Discuss the latest 2018 ACC/AHA Multi-society Guideline on the Management of Blood Cholesterol to reduce the risk of cardiovascular disease
 - **LO 2:** Incorporate current data surrounding non-statin therapy into secondary prevention treatment strategies for patients with the highest cardiovascular risk
 - **LO 3:** Overcome barriers to access for PCSK9 monoclonal antibody therapy
-
- ❖ For all sites, learners achieved substantial and significant improvements across all curriculum Learning Objectives, with changes ranging from 23% to 136%
 - ❖ Uniformly low Pre- and Post-Test scores (< 61%) were measured on the latest guidelines on blood cholesterol management (LO 1), with improvements ranging from 23% to 111%
 - ❖ On incorporating data surrounding non-statin therapy into secondary prevention treatment strategies (LO 2), the strongest improvements (+62%) and highest Post-Test scores (80%) were measured in Uniondale
 - ❖ On overcoming barriers to access for PCSK9 monoclonal antibody therapy (LO 3), the strongest improvements (of 70% and 136%) were measured for the San Diego simulcast and in San Mateo, while the highest Pre- and Post-Test scores were measured in Houston and Uniondale

Learning Objective Analysis, Per Site

Pre-Test Post-Test



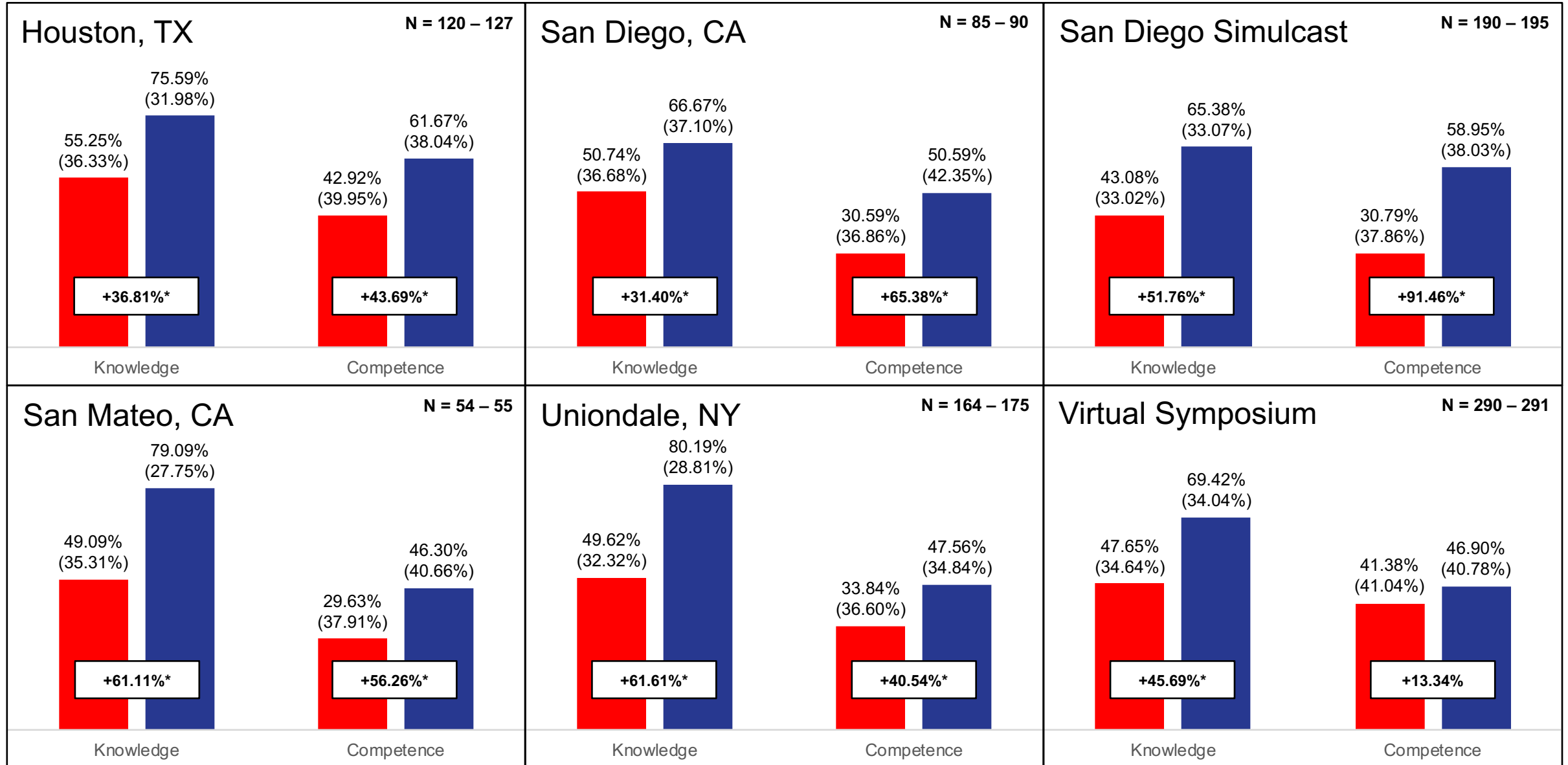
Learning Domain Analysis, Per Site

Pre- and Post-Test Knowledge and Competence scores were independently analyzed for each of the six sites (see next slide)

- ❖ For all sites, learners achieved substantial and significant improvements in Knowledge
- ❖ Improvements in Competence were also measured for each of the sites, which were significant for all except the virtual symposium
- ❖ The greatest increases in Knowledge (61% and 62%) and highest Post-Test average (79% and 80%) were measured in San Mateo and Uniondale
- ❖ Uniformly low to moderate Post-Test scores (46% to 62%) from low Pre-Test scores (30% to 43%) were measured in Competence for all six sites

Learning Domain Analysis, Per Site

Pre-Test Post-Test



Learning Objective Analysis: Onsite vs. Online Audience

- “Live onsite learners” include only those attending in-person meetings
- “Live online learners” include those from both the simulcast and virtual symposium

Learning Objective	Live Onsite Learners				Live Online Learners			
	N	Pre-Test	Post-Test	Change	N	Pre-Test	Post-Test	Change
Discuss the latest 2018 ACC/AHA Multi-society Guideline on the Management of Blood Cholesterol to reduce the risk of cardiovascular disease	428	34.00% (38.45%)	54.56% (36.61%)	+60.47%*	464	35.78% (38.45%)	54.20% (40.59%)	+51.48%*
Incorporate current data surrounding non-statin therapy into secondary prevention treatment strategies for patients with the highest cardiovascular risk	447	51.38% (34.85%)	76.03% (31.83%)	+47.98%*	486	45.82% (34.07%)	67.80% (33.71%)	+47.97%*
Overcome barriers to access for PCSK9 monoclonal antibody therapy	353	44.76% (49.72%)	74.79% (43.42%)	+67.09%*	426	40.85% (49.15%)	61.50% (48.66%)	+50.55%*

- ❖ Onsite and online learners independently achieved substantial and significant improvements, from Pre- to Post-Test, on all three curriculum Learning Objectives
- ❖ Onsite learners had somewhat greater gains, and similar or higher scores at Pre-Test and Post-Test, compared to online learners, for each of the three Objectives

Learning Objective Analysis: Comparison by Profession

Learning Objective	Nurse Practitioners				Physicians			
	N	Pre-Test	Post-Test	Change	N	Pre-Test	Post-Test	Change
Discuss the latest 2018 ACC/AHA Multi-society Guideline on the Management of Blood Cholesterol to reduce the risk of cardiovascular disease	247	33.81% (38.19%)	52.83% (39.89%)	+56.26%*	66	43.18% (39.78%)	63.64% (40.40%)	+47.38%*
Incorporate current data surrounding non-statin therapy into secondary prevention treatment strategies for patients with the highest cardiovascular risk	260	43.53% (33.96%)	66.92% (34.50%)	+53.73%*	68	57.11% (34.81%)	76.96% (29.43%)	+34.76%*
Overcome barriers to access for PCSK9 monoclonal antibody therapy	226	38.05% (48.55%)	59.73% (49.04%)	+56.98%*	62	56.45% (49.58%)	83.87% (36.78%)	+48.57%*

- ❖ Nurse practitioners and physicians both achieved substantial and significant improvements on all three curriculum Learning Objectives, from Pre- to Post-Test
- ❖ Compared to physicians, nurse practitioners had stronger improvements from lower Pre-Test scores on all three Objectives
- ❖ Physicians had higher Post-Test scores compared to nurse practitioners on all three Objectives

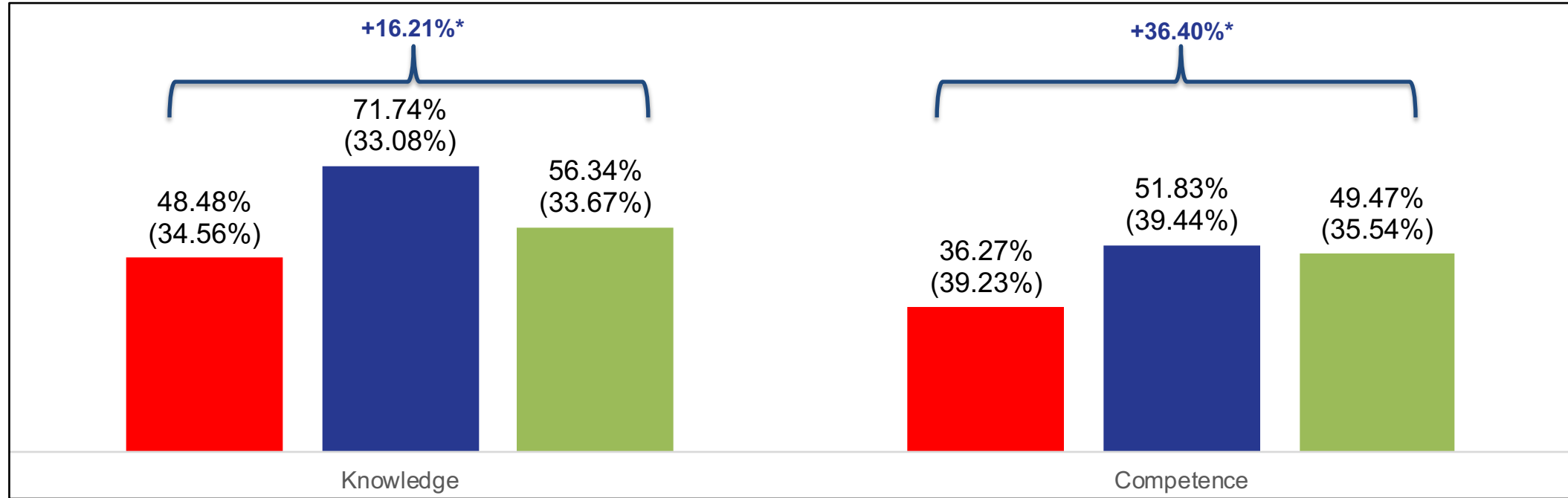
Learning Domain Analysis: Comparison by Profession

Learning domain	Nurse Practitioners				Physicians			
	N	Pre-Test	Post-Test	Change	N	Pre-Test	Post-Test	Change
Knowledge	260	43.53% (33.96%)	66.92% (34.50%)	+53.73%*	68	57.11% (34.81%)	76.96% (29.43%)	+34.76%*
Competence	248	34.27% (39.08%)	50.20% (39.78%)	+46.48%*	70	50.00% (42.26%)	68.57% (37.01%)	+37.14%*

- ❖ Nurse practitioners and physicians both achieved substantial and significant improvements in both Knowledge and Competence, from Pre- to Post-Test
- ❖ Physicians had higher Post-Test scores, but smaller gains from Pre- to Post-Test, compared to nurse practitioners

4-Week Retention Analysis

Pre-Test Post-Test PCA
(N = 284)

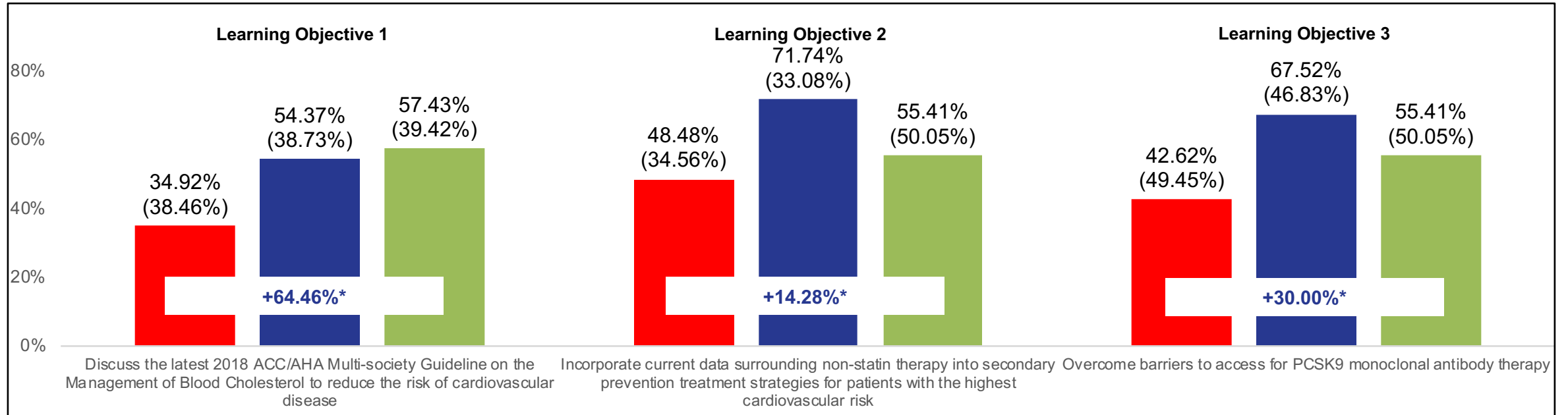


- ❖ The Post Curriculum Assessment (PCA) repeated questions from curriculum Knowledge and Competence domains
- ❖ Statistically significant net gains were measured from Pre-Test to PCA in both Knowledge and Competence
- ❖ In Competence, ongoing improvements in score were measured from Post-Test to PCA, while some score slippage was seen in Knowledge

4-Week Retention Analysis: Learning Objectives

Pre-Test Post-Test PCA

(N = 284)

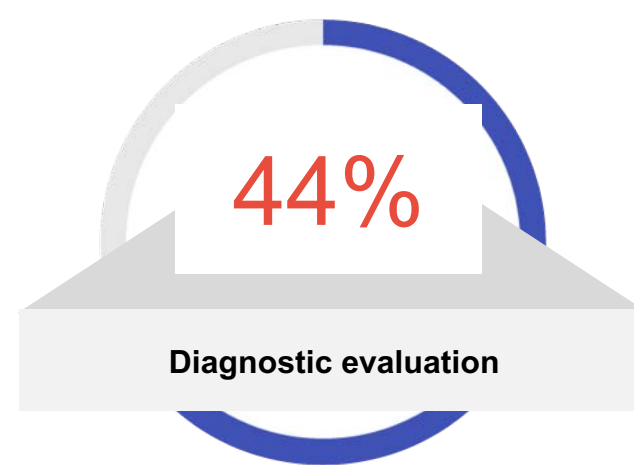
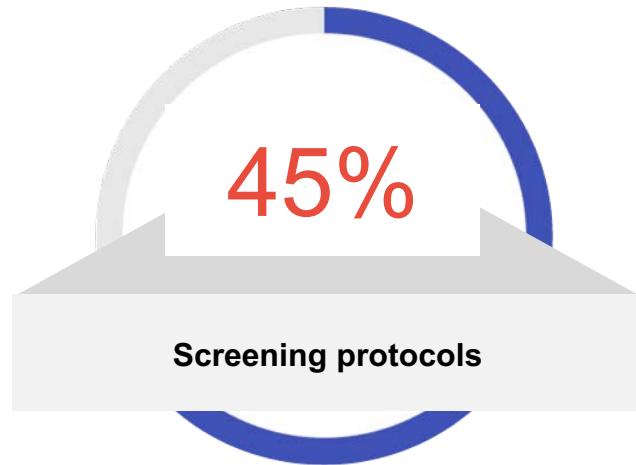
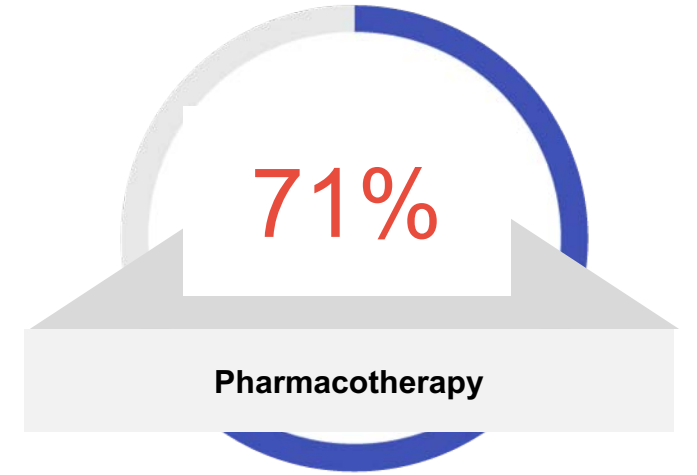
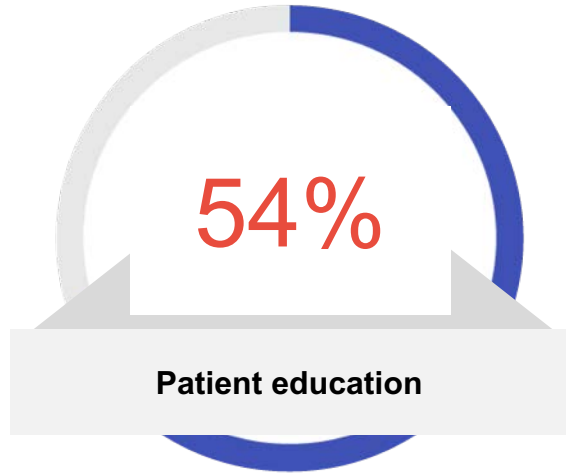


- ❖ Significant net improvements in score between Pre-Test and PCA observations were measured for all three curriculum Learning Objectives
- ❖ Ongoing improvements in score were measured from Post-Test to PCA on latest guidelines for management of blood cholesterol and overcoming barriers to access for PCSK9 monoclonal antibody therapy
- ❖ For all curriculum Learning Objectives, low to moderate PCA scores reflect opportunities for further education in this area

(4-week Post Assessment)

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

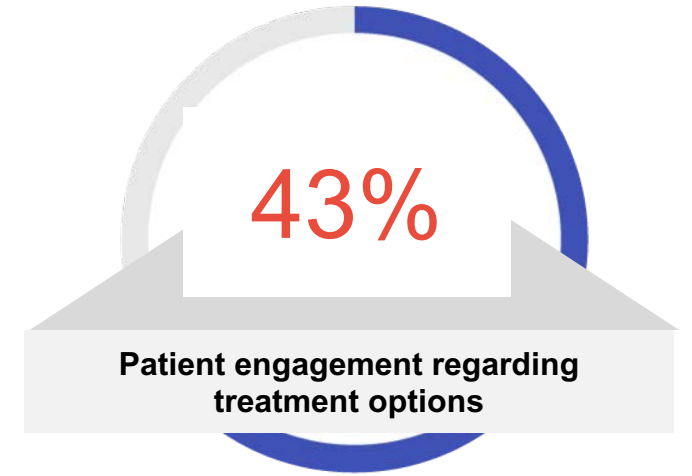
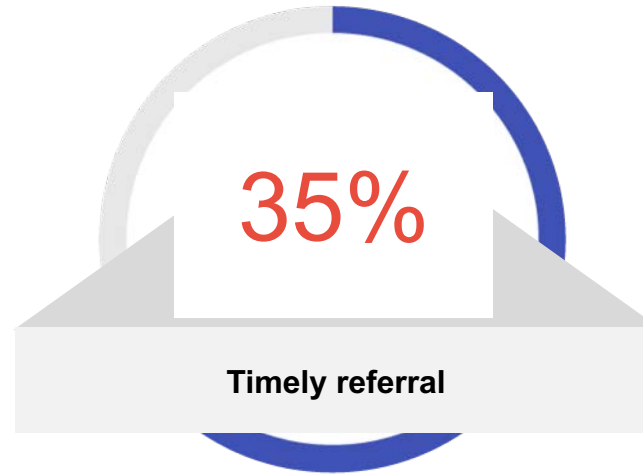
N=284



(4-week Post Assessment)

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

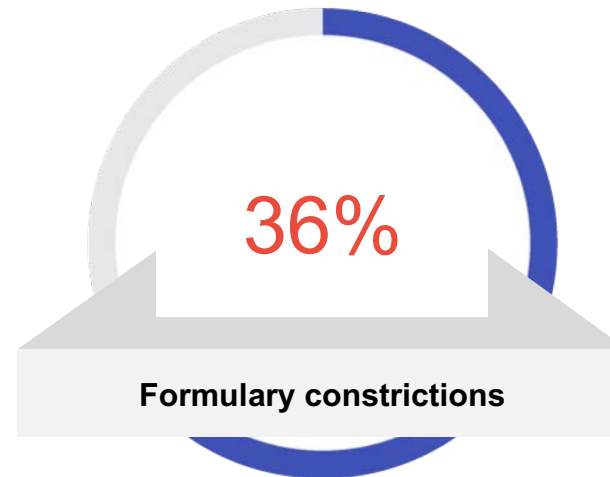
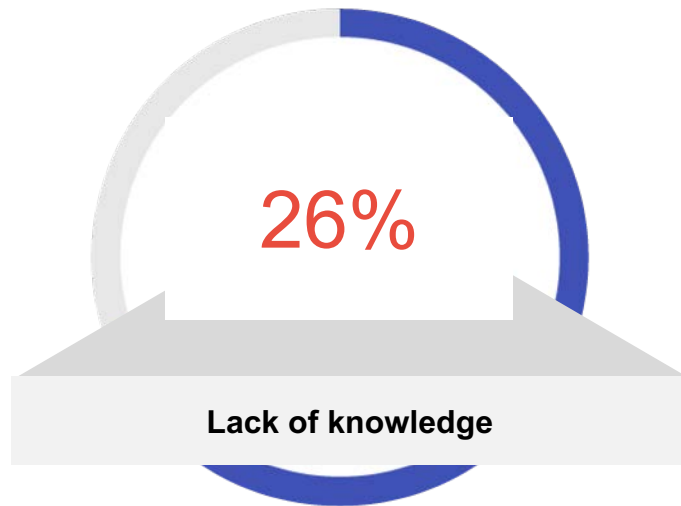
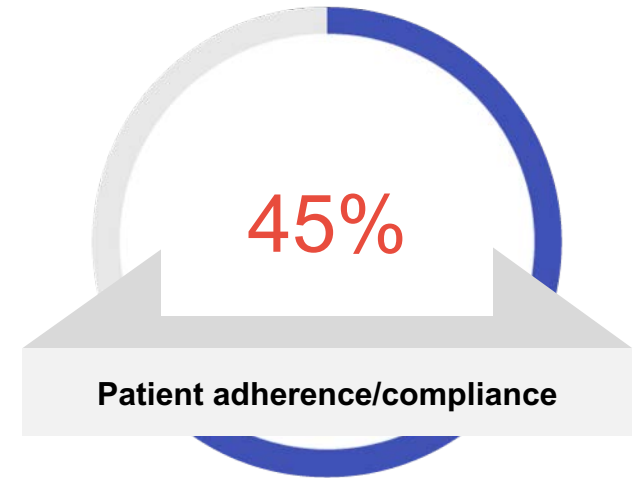
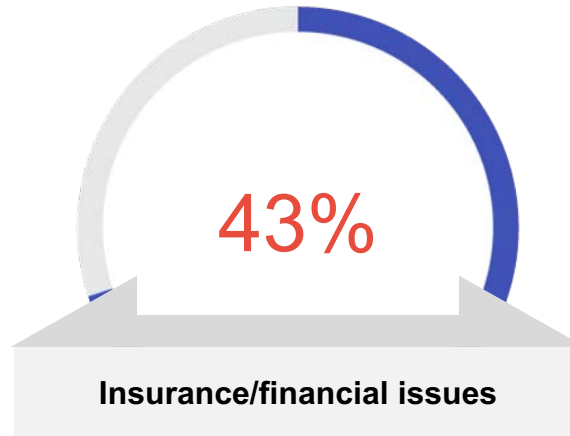
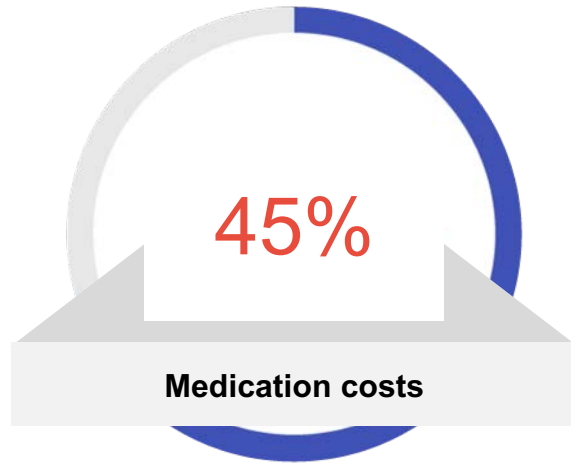
N=284



(4-week Post Assessment)

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

N=284



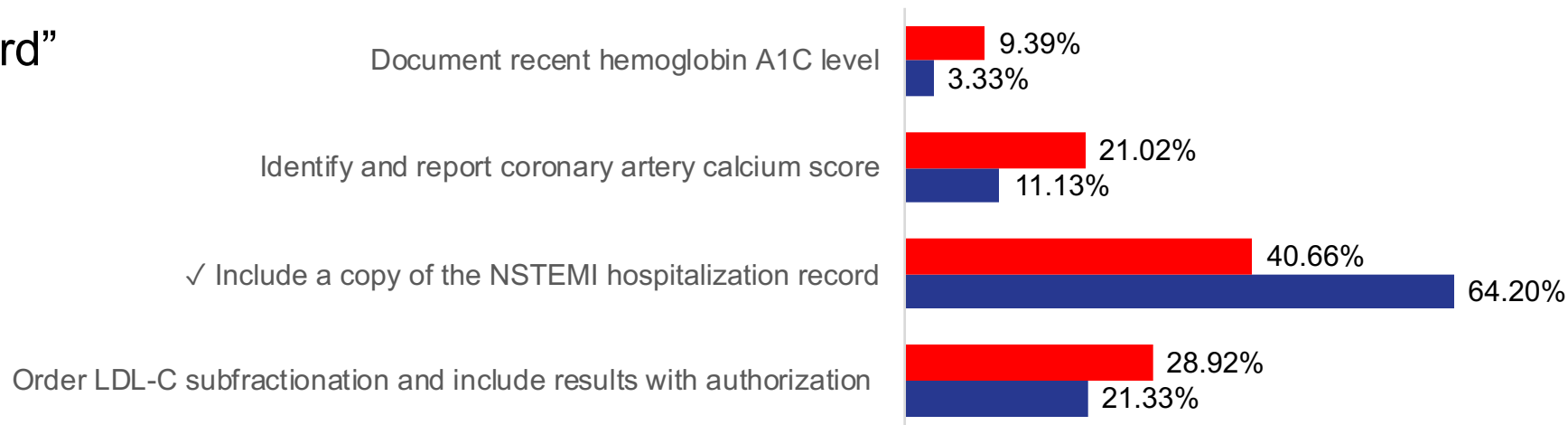
Identified Learning Gap 1 of 3: *Obtaining approval for PCSK9i therapy*

Despite improvements in score on a Competence item asking learners what might facilitate prior approval for PCSK9i therapy for a given patient, low scores were observed at Post-Test

70 y/o overweight woman, PMH: NSTEMI 6 months ago, hypertension, type 2 diabetes, LDL-C 84 mg/dL on atorvastatin 80 mg and ezetimibe 10 mg, PCSK9 inhibitor prior approval rejected. Which of the following might facilitate prior approval for PCSK9 inhibitor therapy for this patient?

Results:

- At Post-Test, 64% of learners correctly answered: “Include a copy of the NSTEMI hospitalization record”



Identified Learning Gap 2 of 3:

Engaging in appropriate risk discussion with patients

On a Competence item where learners were asked whether to consider statin therapies, learners struggled at Post-Test to identify the need to discuss the risk of moderate-intensity statin therapy

A 57 y/o woman presents for a checkup. She has a history of obesity, hypertension, prediabetes, premature menopause, and LDL-C 168 mg/dL. Estimate of 10-year ASCVD risk is 6%. She is currently not taking lipid-lowering therapy, but adheres to a diet low in saturated fats and carbohydrates. According to the 2018 ACC/AHA guidelines, which of the following is correct?

Results:

- At Post-Test, 35% of learners correctly answered: “Engage in risk discussion regarding moderate-intensity statin therapy”

Initiate statin to reduce LDL-C by $\geq 50\%$



Engage in risk discussion regarding high-intensity statin therapy



✓ Engage in risk discussion regarding moderate-intensity statin therapy



Emphasize lifestyle interventions and do not consider statin therapy at this time



Identified Learning Gap 3 of 3:

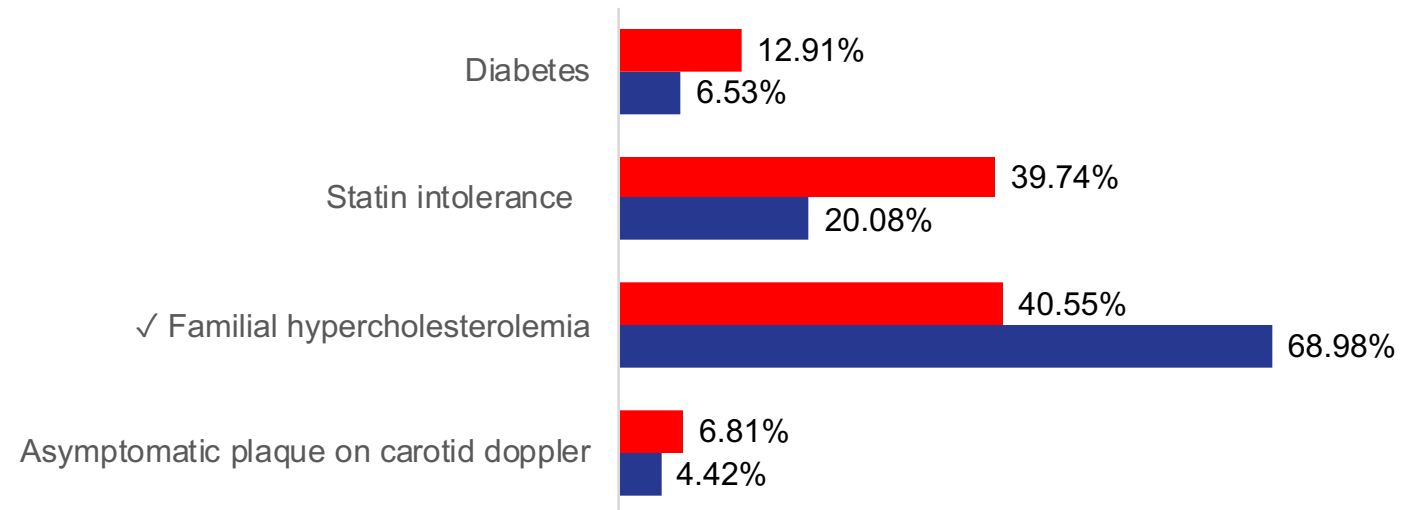
Role of familial hypercholesterolemia in treatment selection

On a Knowledge item about indications for PCSK9i therapy, learners struggled at Post-Test to identify familial hypercholesterolemia as an approved indication

Which of the following is an approved indication for PCSK9 inhibitor therapy in a patient with dyslipidemia?

Results:

- At Post-Test, 69% of learners correctly answered: “Familial hypercholesterolemia”



Overall Educational Impact

- ❖ Significant improvements in score of 48% and 43% were seen in Knowledge and Competence
 - These increases were stronger for live onsite learners compared to live online learners, with onsite learners also achieving higher Pre- and Post-Test scores
 - On a follow-up assessment, ongoing improvements from Post-Test to follow-up were seen in Competence, with some reduction in Knowledge score
 - Pre-Test scores on Confidence and practice strategy questions were moderate (2.74 and 3.19), reflecting learner awareness of their gaps in Knowledge and Competence in this area
- ❖ Significant gains ranging from 48% to 58% were measured across all three Learning Objectives. The greatest improvement was measured on overcoming barriers for PCSK9 monoclonal antibody therapy
 - The lowest Pre- and Post-Test scores were measured on discussion of recent guidelines on management of blood cholesterol
- ❖ The analysis of the Knowledge and Competence domains identified three **persistent learning gaps related to management of patients with hyperlipidemia**
 - Low scores at Post-Test (64%) were measured on a Competence item on **strategies for obtaining approval for PCSK9 inhibitor therapy**
 - On another Competence item about **engaging in appropriate risk discussion with patients**, learners struggled at Pre- and Post-Test (29% to 35%)
 - A Knowledge item assessed the ability of learners to identify the **role of familial hypercholesterolemia in treatment selection** for a patient with hyperlipidemia, and resulted in low scores (69%) at Post-Test

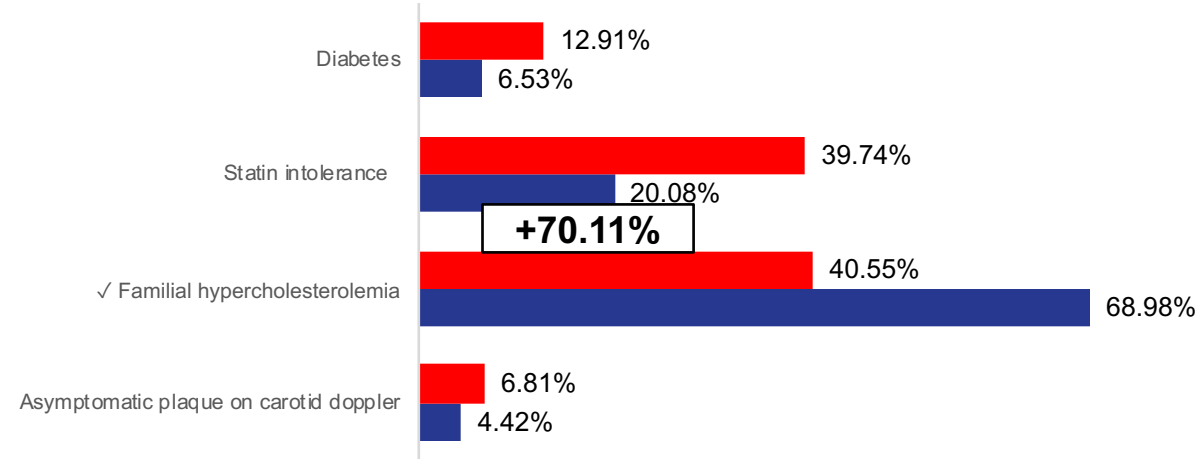
Appendix

Knowledge Items

Pre-Test
Post-Test

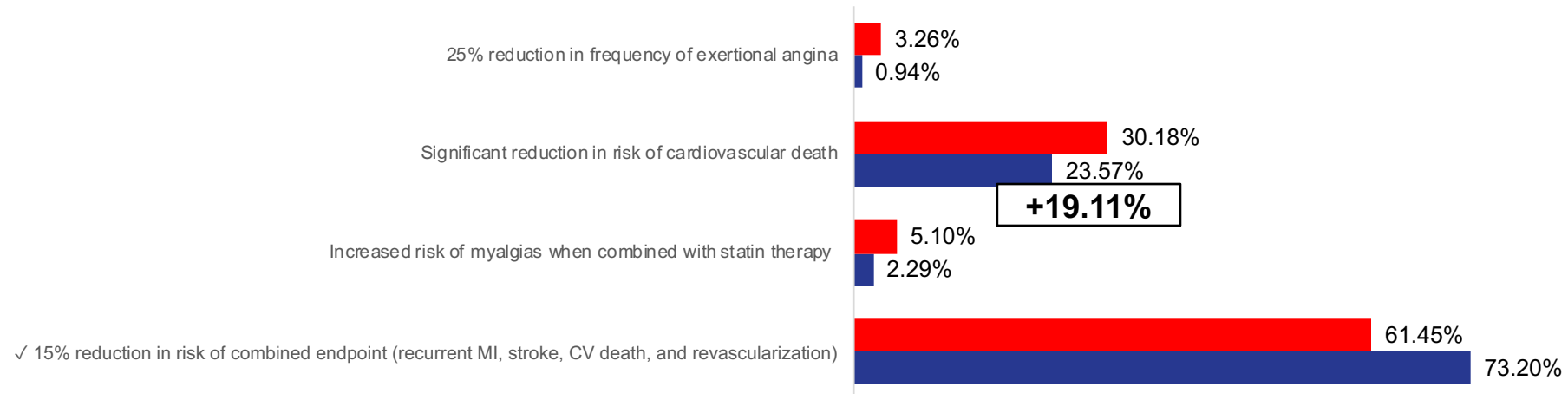
Which of the following is an approved indication for PCSK9 inhibitor therapy in a patient with dyslipidemia?

N = 984 – 996



Clinical outcomes studies of PCSK9 inhibitors have reported which of the following?

N = 921 – 959



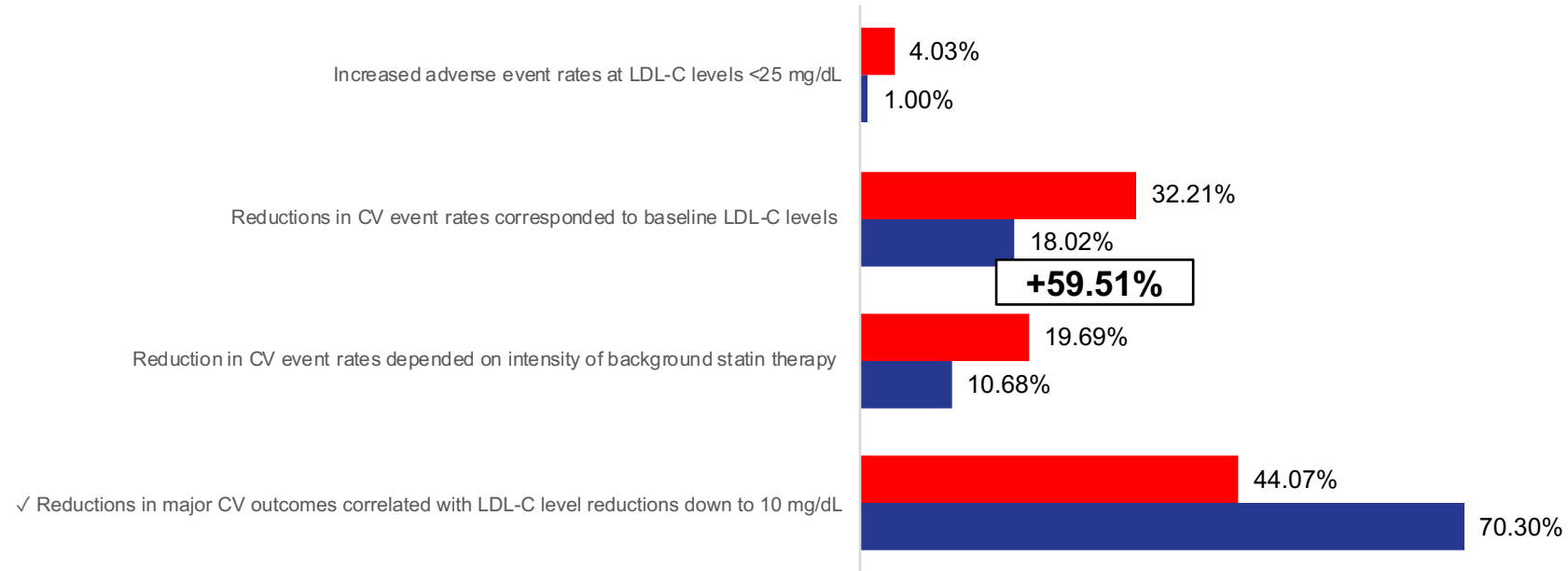
Note: data are not matched.
Correct answer is designated by a ✓.

Knowledge Items

Pre-Test
Post-Test

Clinical outcomes studies of PCSK9 inhibitors have reported which of the following?

N = 894 – 899

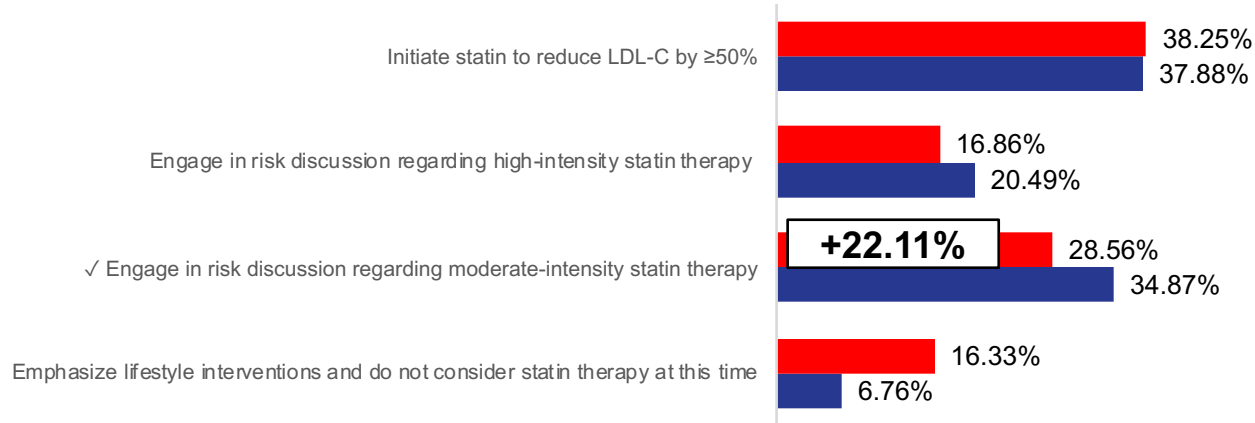


Competence Items

Pre-Test
Post-Test

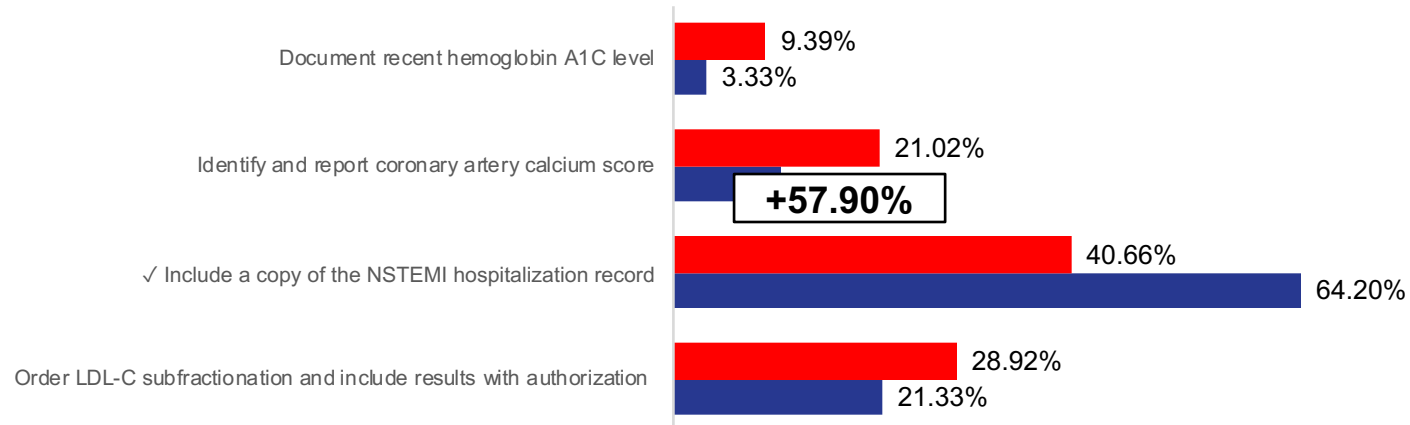
A 57 y/o woman presents for a checkup. She has a history of obesity, hypertension, prediabetes, premature menopause, and LDL-C 168 mg/dL. Estimate of 10-year ASCVD risk is 6%. She is currently not taking lipid-lowering therapy, but adheres to a diet low in saturated fats and carbohydrates. According to the 2018 ACC/AHA guidelines, which of the following is correct?

N = 932 – 949



70 y/o overweight woman, PMH: NSTEMI 6 months ago, hypertension, type 2 diabetes, LDL-C 84 mg/dL on atorvastatin 80 mg and ezetimibe 10 mg, PCSK9 inhibitor prior approval rejected. Which of the following might facilitate prior approval for PCSK9 inhibitor therapy for this patient?

N = 937 – 961

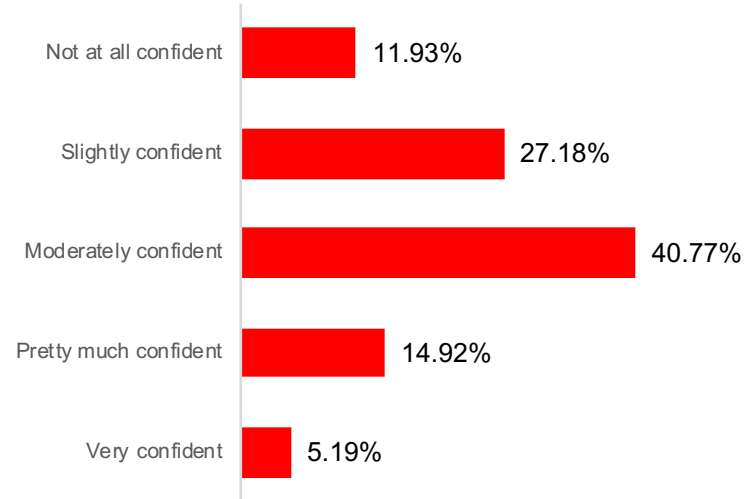


Confidence and Practice Strategy Items

Pre-Test

Please rate your confidence in your ability to apply the 2018 ACC/AHA blood cholesterol guidelines to the care of your patients:

N = 905



How often do you consider non-statin therapies in high-risk patients not at recommended LDL-C target, despite maximally tolerated statin therapy?

N = 833

