NACE *Conversations* in Primary Care 2019

Final Live Outcomes Report

Secondary Cardiovascular Risk Reduction: Incorporating Evolving Data to Individualize Care

Amgen, Inc. • IME-172560

January 23, 2020

RealCME

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NACE *Conversations* in Primary Care

Secondary Cardiovascular Risk Reduction: Incorporating Evolving Data to Individualize Care

2,382 Participants

3 Activities

2,236 certificates issued to date

This education has the potential to impact **1,857,960** patients with hyperlipidemia on an annual basis.

30,966–40,494 Patients Weekly

2019 Conversations Activity	Date	Participants
Conversations in Primary Care 2019 Episode 1	2/9/19	867
Conversations in Primary Care 2019 Episode 2	3/2/19	762
Conversations In Primary Care 2019 Episode 3	3/30/19	723
Total		**2,382**

Speaker

Karol Watson, MD, PhD
Professor of Medicine/Cardiology
Co-director, UCLA Program in Preventive Cardiology
Director, UCLA Barbra Streisand Women's Heart Health Program
David Geffen School of Medicine at UCLA
John Mazziotta, M.D., Ph.D. Term Chair in Medicine.

Secondary Cardiovascular Risk Reduction: Incorporating Evolving Data to Individualize Care

COURSE SUMMARY

Cost: Free

Start Date: 02/19/2019

Expiration Date: 02/18/2020

Target Audience: Primary Care Physicians, Nurse Practitioners, Physicians Assistants

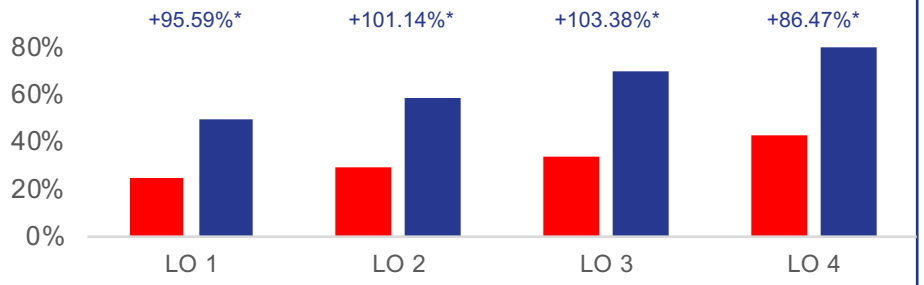
Format: Webcast

Estimated Time To Complete CME Activity: 1 hour

Credit(s): 1.0 *AMA PRA Category 1 Credit™* 1.0 AANP Contact hour including 0.75 pharmacology hours

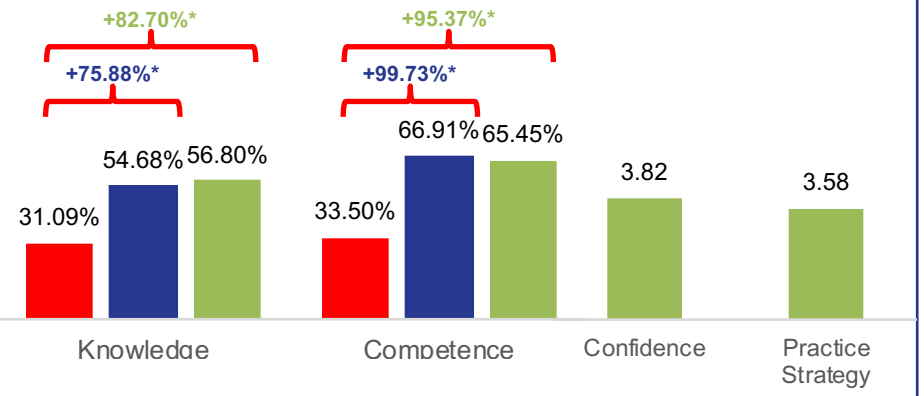
Hardware/Software Requirements: Any web browser

Learning Gains Across Objectives



- **LO 1, 96%* Improvement:** Describe the findings from recent trials of PCSK9i hypercholesterolemia treatments on cardiovascular outcomes
- **LO 2, 101%* Improvement:** Discuss current guidelines and recommendations for the management of hyperlipidemia in high - risk patients
- **LO 3, 103%* Improvement:** Incorporate current data into secondary prevention treatment strategies for patients with the highest cardiovascular risk
- **LO 4, 86%* Improvement:** Recognize barriers to access for PCSK9 monoclonal antibody therapy and discuss strategies to overcome them

Learning Domain Analysis



- Substantial and significant improvements were measured from Pre- to Post-Test in both Knowledge and Competence
- These gains were seen across all curriculum Knowledge and Competence items, with uniform gains of 72% to 115%, form Pre- to Post-Test
- Confidence and practice strategy ratings, collected only at follow-up, were moderate

Persistent Learning Gaps/Needs

Guidelines for management of risk associated with statin and PCSK9i therapy

On two Knowledge questions on the risk of cardiovascular events associated with PCSK9 inhibitor and statin therapies, learners struggled to answer correctly at Post-Test.

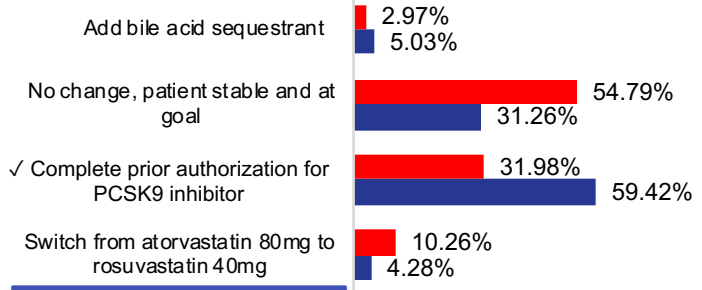
In the FOURIER and ODYSSEY outcomes trials, what was the relative reduction in risk for major cardiovascular events with PCSK9 inhibitors compared to placebo?
At Post-Test, only 47% of learners correctly answered: "15%"

According to the 2018 Blood Cholesterol guidelines, for patients in which category of estimated 10-year ASCVD risk should risk enhancers be considered when discussing potential statin therapy for primary prevention?
At Post-Test, only 35% of learners correctly answered: "5% to 20%"

Guidelines for management of risk associated with statin and PCSK9i therapy

On two Knowledge questions on the risk of cardiovascular events associated with PCSK9 inhibitor and statin therapies, learners struggled to answer correctly at Post-Test.

A 67-year-old man with a history of NSTEMI (2 years and 6 months ago), hypertension, and dyslipidemia presents for a checkup. He is feeling well. LDL-C is 73 mg/dL. Meds: atorvastatin 80 mg qd, ezetimibe 10mg qd, metoprolol tartrate 100 mg bid, lisinopril 20 mg qd, and aspirin 81 mg qd. According to the 2018 Blood Cholesterol guidelines, which of the following is most appropriate?



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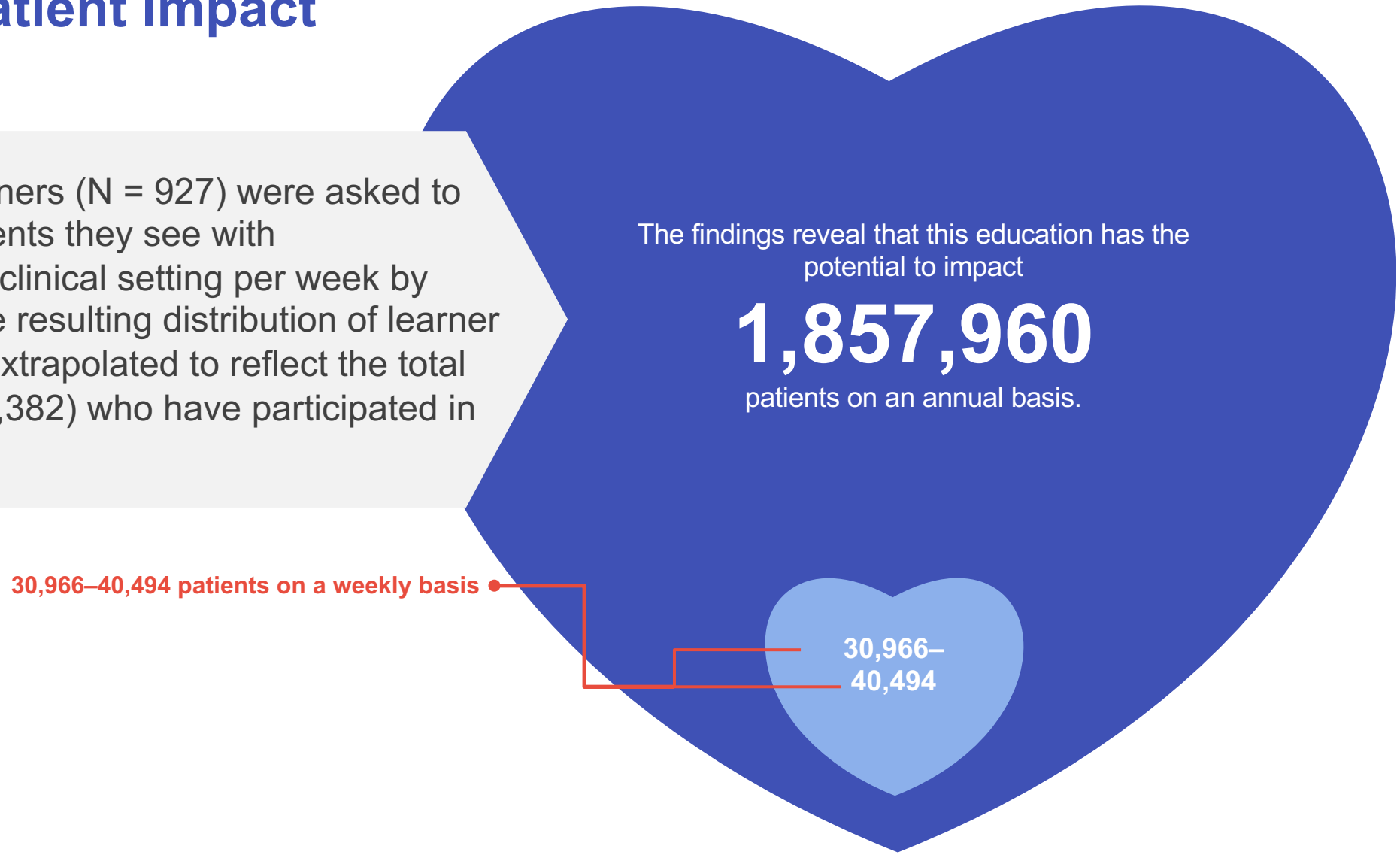
Curriculum Patient Impact

In the evaluation, learners (N = 927) were asked to report how many patients they see with hyperlipidemia 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 (2,382) who have participated in the activities.



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Director, UCLA Barbra Streisand Women's Heart Health Program
David Geffen School of Medicine at UCLA
Los Angeles, CA

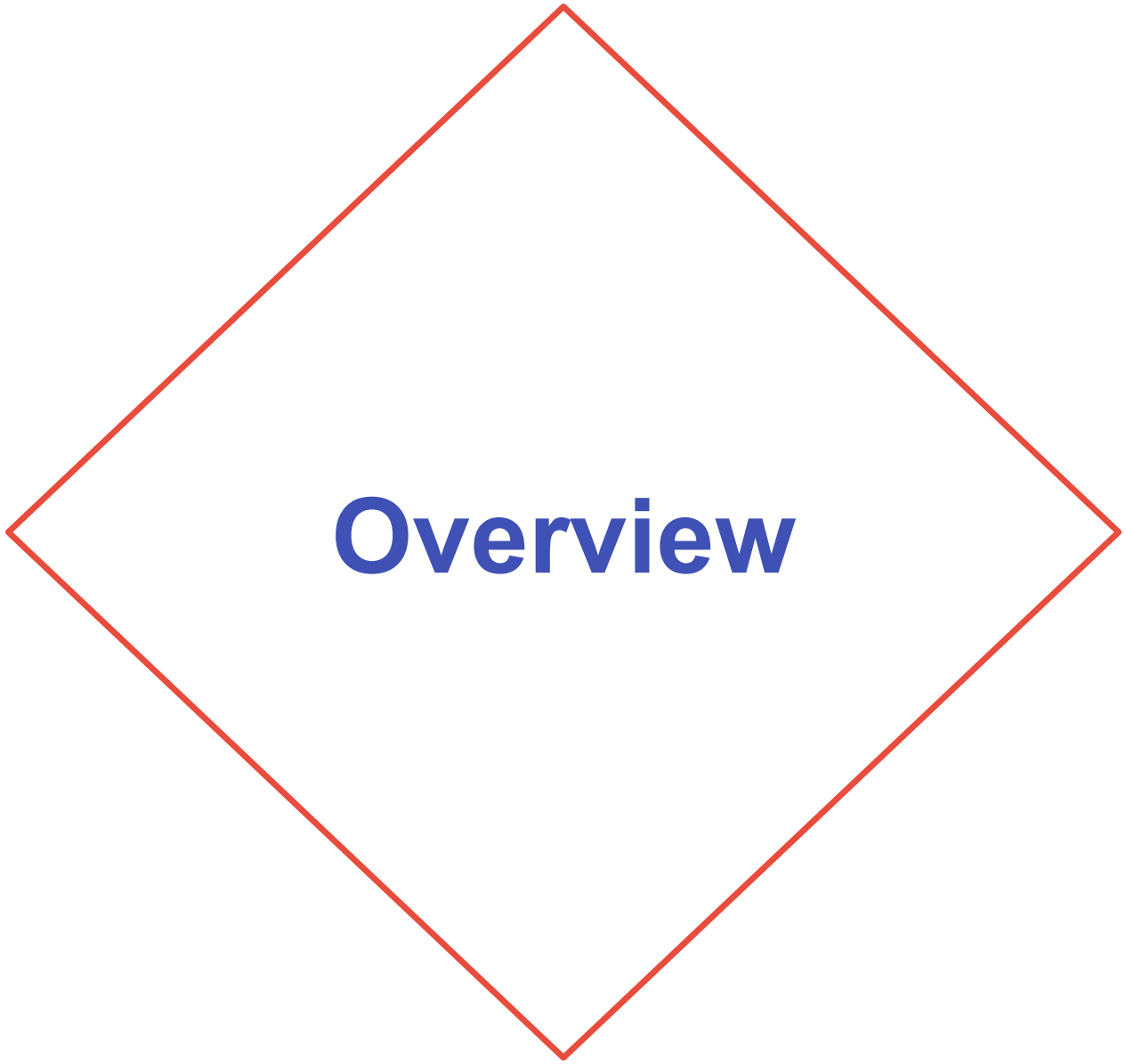
David N. Smith, MD
Clinical Assistant Professor of Medicine Yale University
Associate Professor of Medicine, Wingate University
Adjunct Professor at UNC Chapel Hill
Charlotte, NC

NACE *Conversations* in Primary Care 2019

Commercial Support

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

- Actelion Pharmaceuticals US, Inc.
- Amgen, Inc.
- Lilly USA, LLC
- Novo Nordisk, Inc.
- Sanofi Genzyme and Regeneron Pharmaceuticals
- Sanofi US and Regeneron Pharmaceuticals
- Takeda Pharmaceuticals U.S.A., Inc. and Lundbeck
- Intercept Pharmaceuticals, Inc.
- Shire
- Avanir Pharmaceuticals
- Eisai
- Galderma


Overview

Learning Objectives

- Describe the findings from recent trials of PCSK9i hypercholesterolemia treatments on cardiovascular outcomes
- Discuss current guidelines and recommendations for the management of hyperlipidemia in high - risk patients
- Incorporate current data into secondary prevention treatment strategies for patients with the highest cardiovascular risk
- Recognize barriers to access for PCSK9 monoclonal antibody therapy and discuss strategies to overcome them

NACE *Conversations* in Primary Care 2019

Curriculum Overview

Three Live Virtual CME Symposia



Enduring CME Symposium Webcast

Speaker

Karol Watson, MD, PhD
Professor of Medicine/Cardiology
Co-director, UCLA Program in Preventive Cardiology
Director, UCLA Barbra Streisand Women's Heart Health Program
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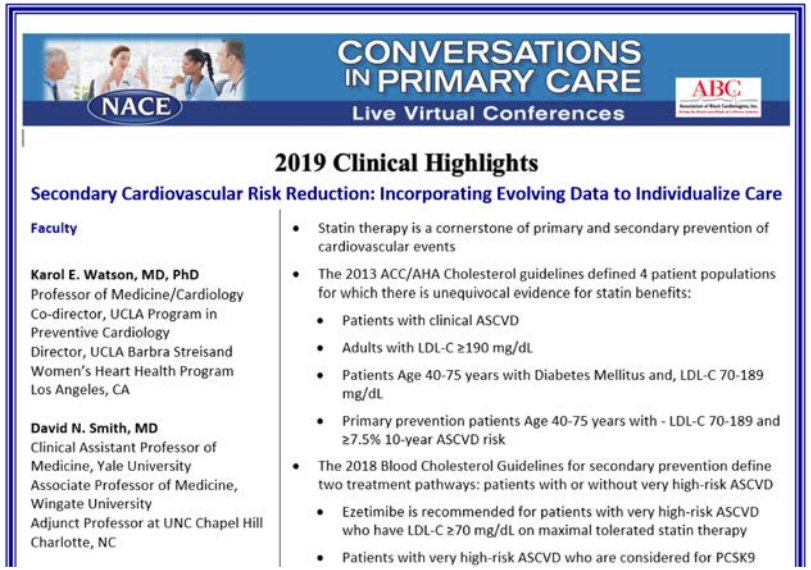
Hardware/Software Requirements: Any web browser

Clinical Highlights eMonograph

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

Live Virtual Conferences

ABC

2019 Clinical Highlights

Secondary Cardiovascular Risk Reduction: Incorporating Evolving Data to Individualize Care

Faculty

Karol E. Watson, MD, PhD
Professor of Medicine/Cardiology
Co-director, UCLA Program in Preventive Cardiology
Director, UCLA Barbra Streisand Women's Heart Health Program
Los Angeles, CA

David N. Smith, MD
Clinical Assistant Professor of Medicine, Yale University
Associate Professor of Medicine, Wingate University
Adjunct Professor at UNC Chapel Hill
Charlotte, NC

- Statin therapy is a cornerstone of primary and secondary prevention of cardiovascular events
- The 2013 ACC/AHA Cholesterol guidelines defined 4 patient populations for which there is unequivocal evidence for statin benefits:
  - Patients with clinical ASCVD
  - Adults with LDL-C ≥190 mg/dL
  - Patients Age 40-75 years with Diabetes Mellitus and, LDL-C 70-189 mg/dL
  - Primary prevention patients Age 40-75 years with - LDL-C 70-189 and ≥7.5% 10-year ASCVD risk
- The 2018 Blood Cholesterol Guidelines for secondary prevention define two treatment pathways: patients with or without very high-risk ASCVD
  - Ezetimibe is recommended for patients with very high-risk ASCVD who have LDL-C ≥70 mg/dL on maximal tolerated statin therapy
  - Patients with very high-risk ASCVD who are considered for PCSK9

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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

Participation

2019 Conversations Activity	Date	Participants
Conversations In Primary Care 2019 Episode 1	2/9/19	867
Conversations In Primary Care 2019 Episode 2	3/2/19	792
Conversations In Primary Care 2019 Episode 3	3/30/19	723
Total		**2,382**

Level 1
Participation
Demographics
Patient Reach

Participation

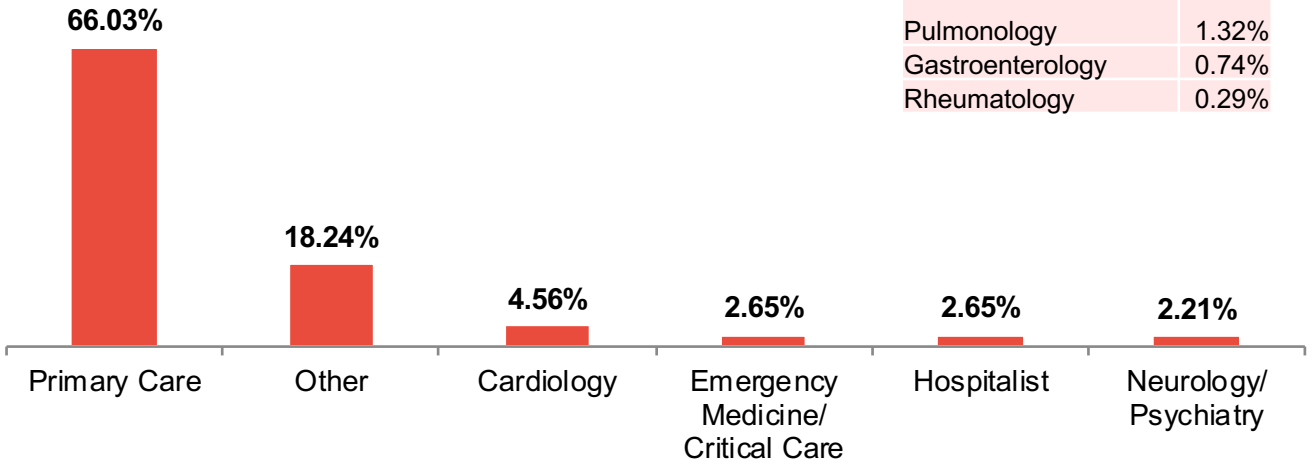
2,382
Total Attendees

3 Activities

N = 680 – 927

Level 1: Demographics and Patient Reach

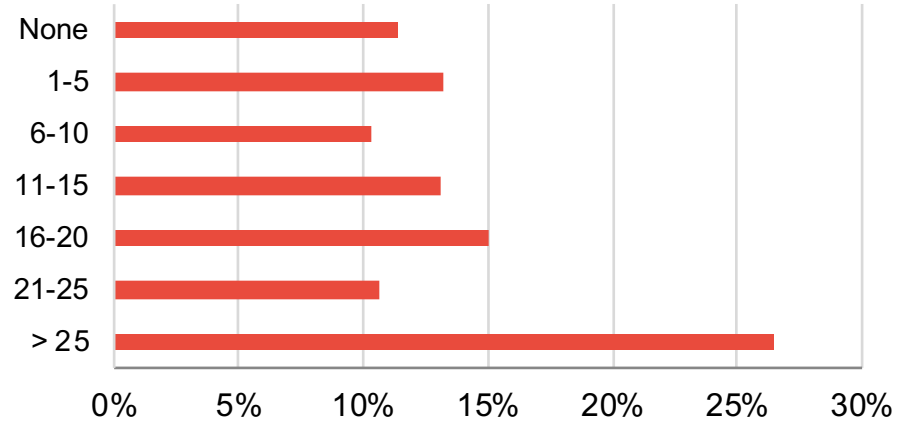
Specialty



Under 2%	
Endocrinology	1.32%
Pulmonology	1.32%
Gastroenterology	0.74%
Rheumatology	0.29%

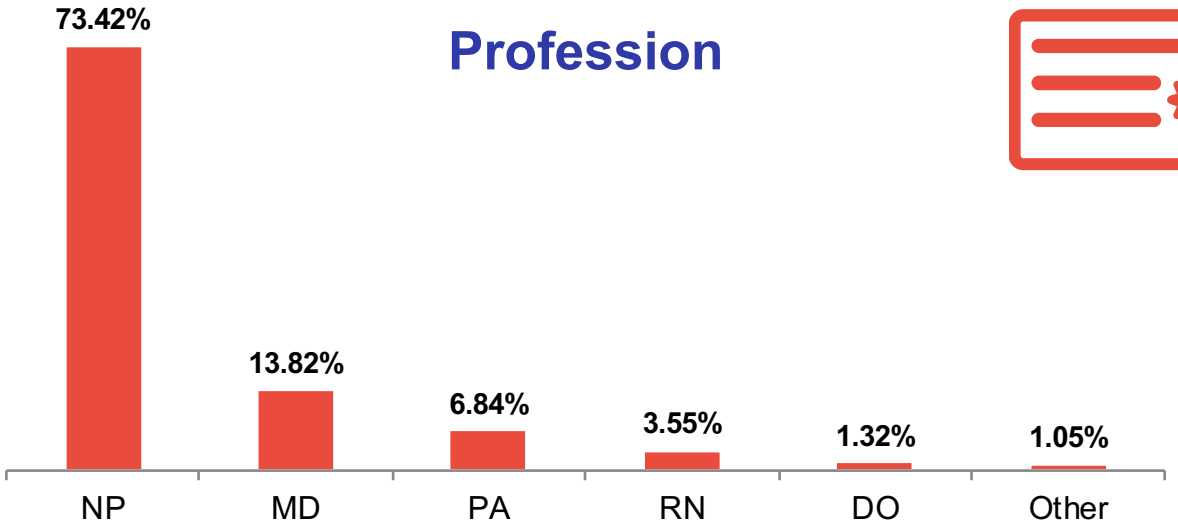
Patient Care Focus: 94%

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

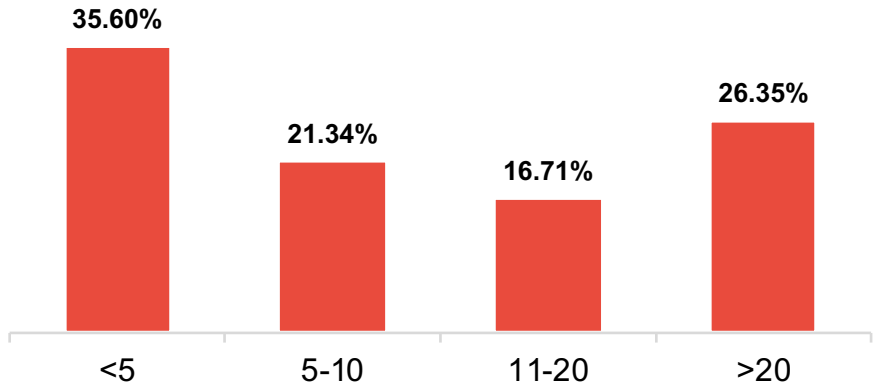


Average number of patients seen each week with hyperlipidemia per clinician: 15

Profession



Years in Practice



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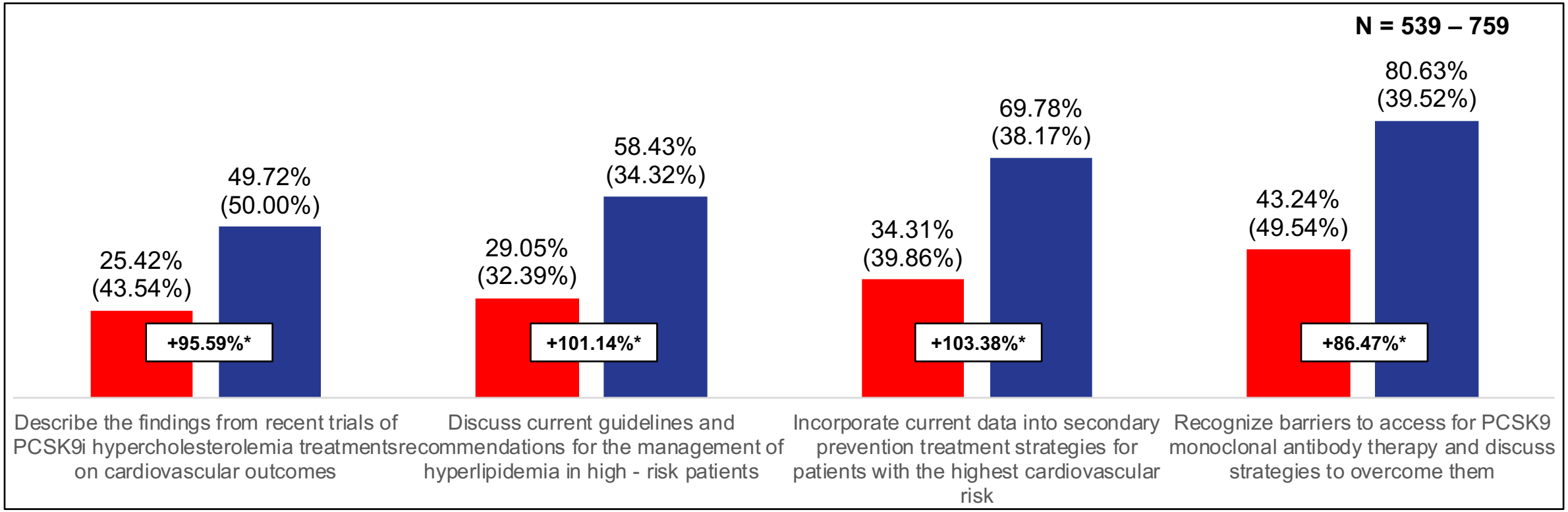
Level 2-5:
Outcomes Metrics

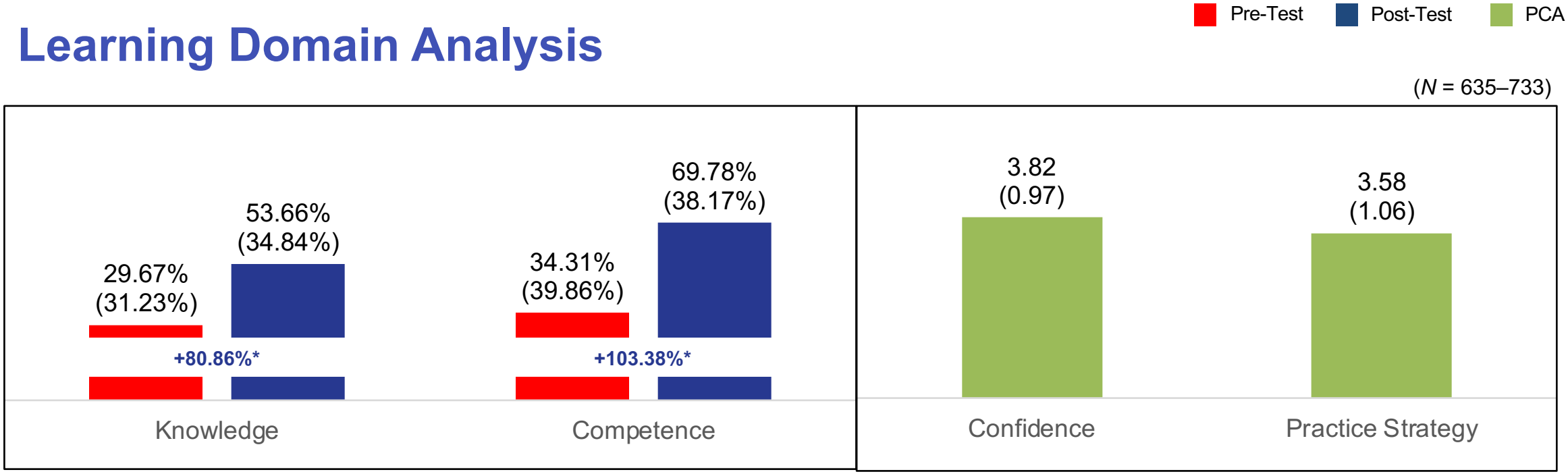
Learning Objective Analysis



- On each of the four curriculum Learning Objectives, learners achieved substantial and significant improvements in score, from Pre- to Post-Test
- High scores at Post-Test were measured on recognizing and overcoming barriers to PCSK9 therapy, but Post-Test scores were low on the other three Objectives despite strong improvements
  - Low scores on findings from recent trials of PCSK9i treatments were driven by an item about the FOURIER and ODDYSSEY trials
  - Low scores on guidelines and recommendations for high-risk hyperlipidemia patients were driven by a Knowledge item on the 2018 blood cholesterol guidelines on ASCVD risk

Note: data are matched.
* indicates significance, $p < 0.05$.

Learning Domain Analysis

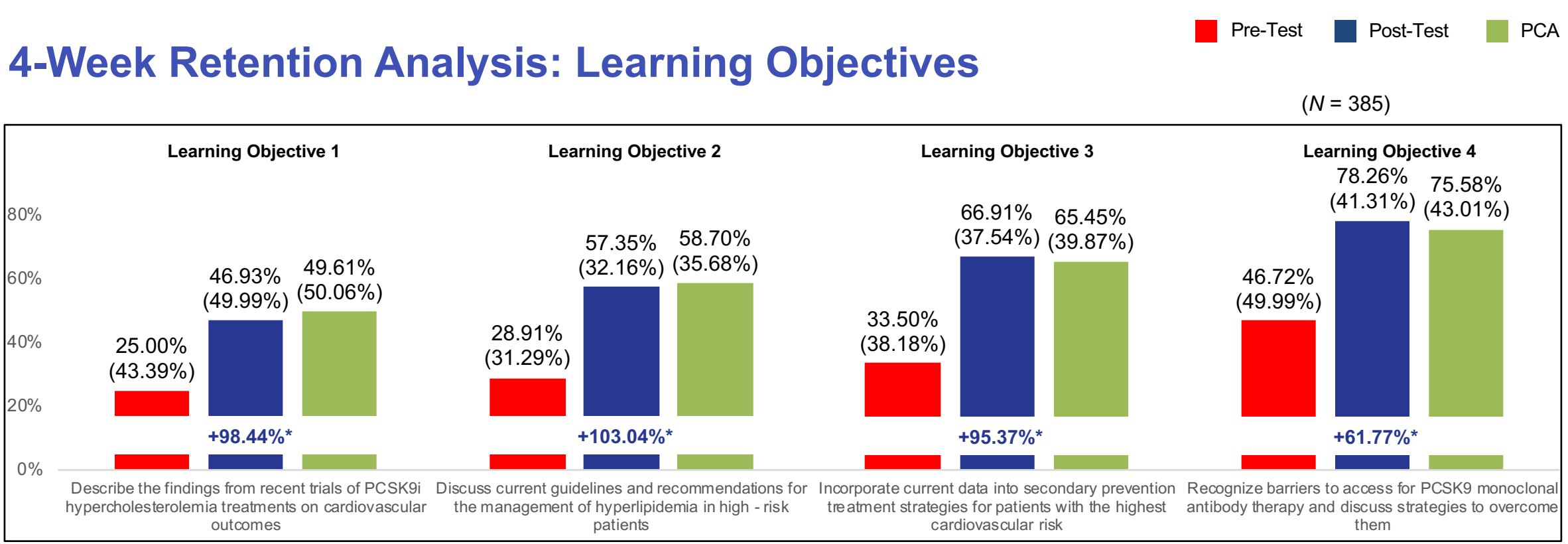


- Substantial and significant improvements were measured from Pre- to Post-Test in both Knowledge and Competence
- These gains were seen across all curriculum Knowledge and Competence items, with uniform gains of 72% to 115%, form Pre- to Post-Test
- Confidence and practice strategy ratings, collected only at follow-up, were moderate

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

significant at the p ≤ 0.05 level, matched data

4-Week Retention Analysis: Learning Objectives

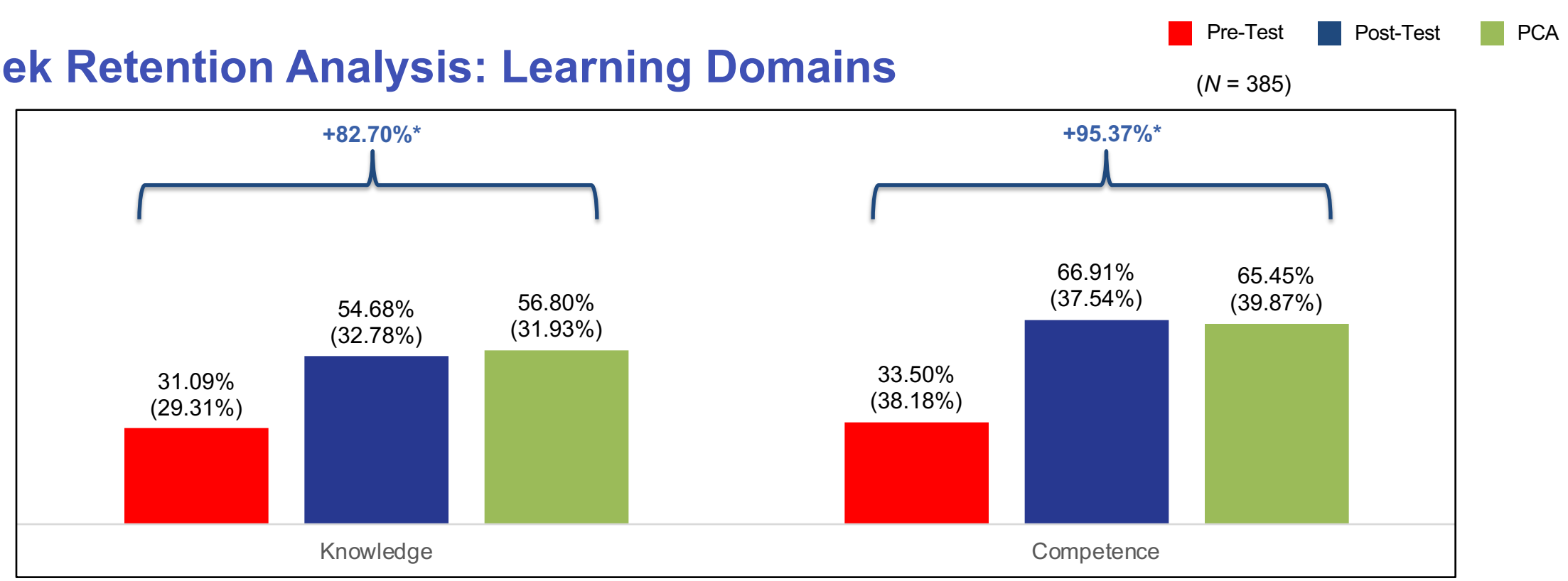


- Significant improvements in score between Pre-Test and PCA observations were measured for all curriculum Learning Objectives
- Across all Learning Objectives, improvements in score measured from Pre- to Post-Test were well retained, with only small changes in score between Post-Test and PCA
- For all Learning Objectives, low to moderate PCA scores reflect opportunities for further education 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 ≤ 0.05 level

4-Week Retention Analysis: Learning Domains



At follow-up:

- In addition to collecting Confidence and Practice data for the curriculum, the Post Curriculum Assessment (PCA) repeated 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 (83%) and Competence (95%)
- In both Knowledge and Competence, only small changes in score were observed from Post-Test to PCA, representing strong retention of content in these domains

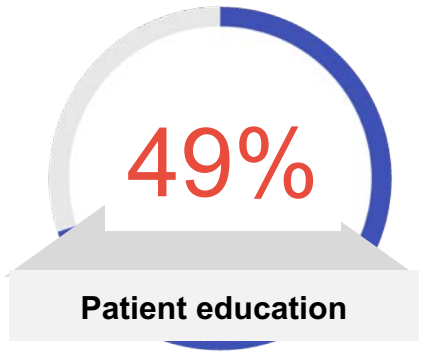
Note: data is matched; learners with a score for the given domain on both the Pre-Test and PCA are included

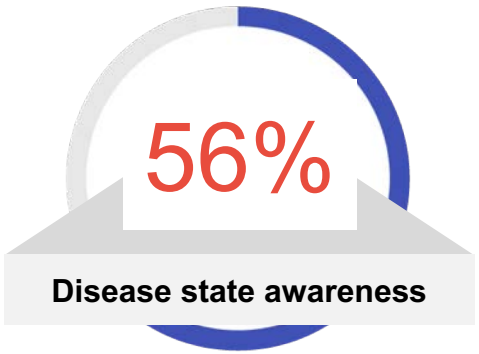
***significant at the p ≤ 0.05 level**

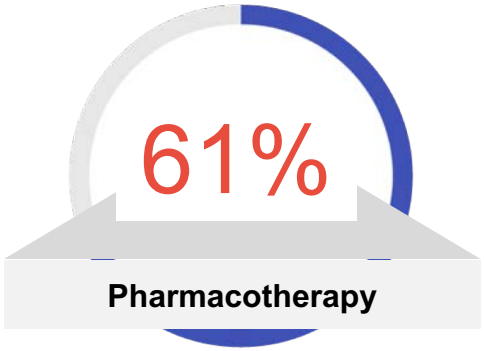
(4-week Post Assessment)

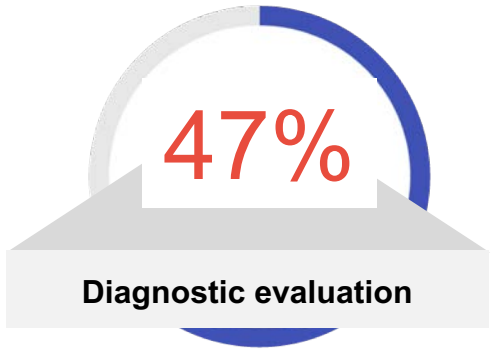
Please select the specific areas of *skills, or practice behaviors*, you have improved regarding the treatment of patients with hyperlipidemia since this CME activity. (Select all that apply.)

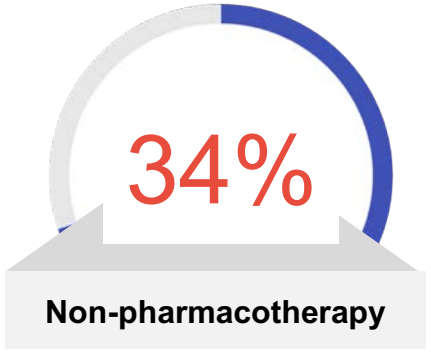
N=423

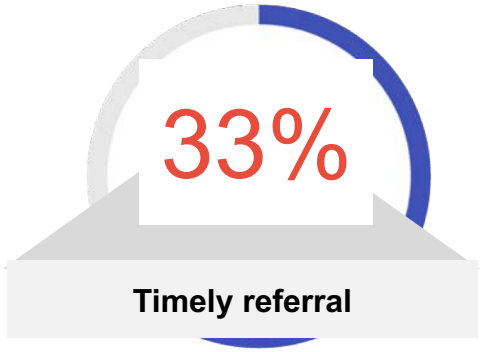


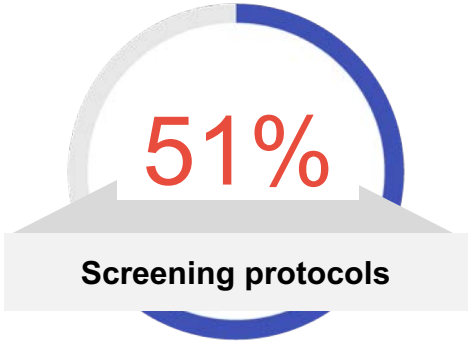


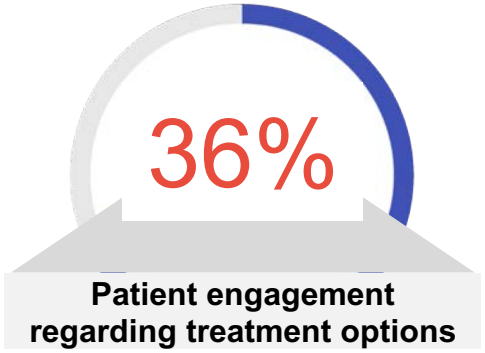








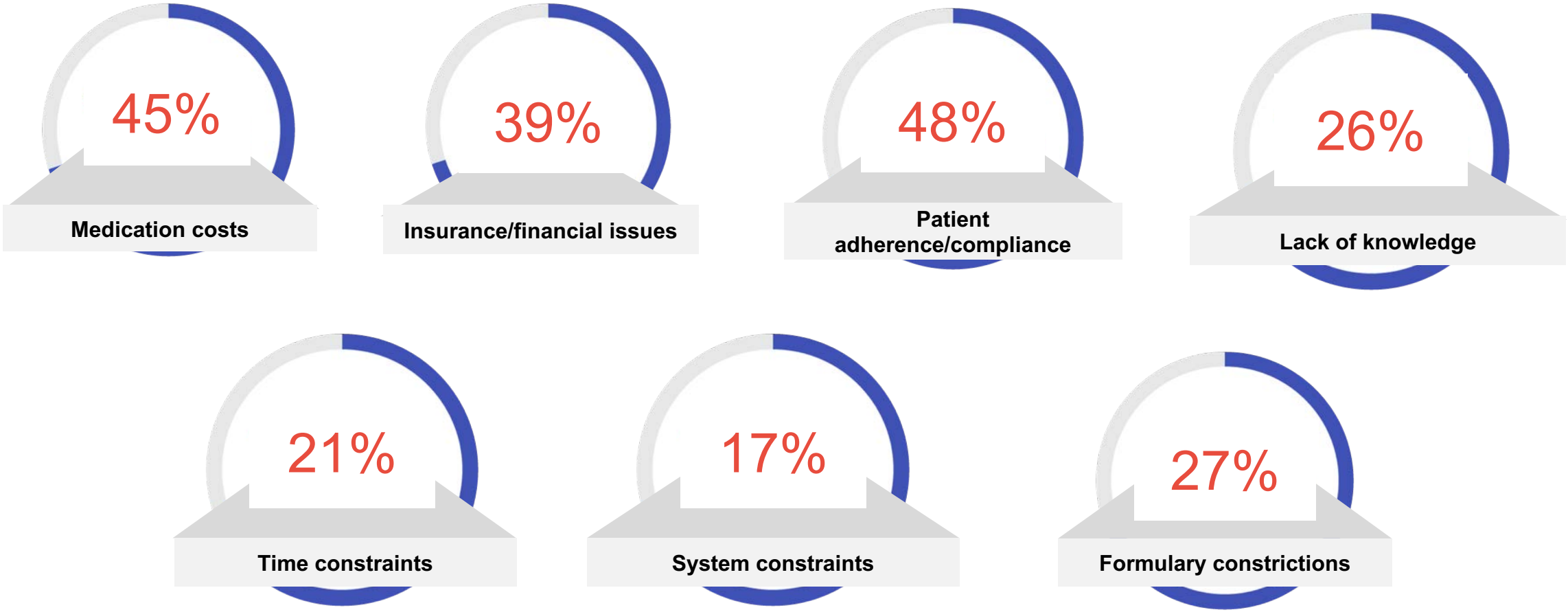




(4-week Post Assessment)

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=423



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 findings from recent trials of PCSK9i hypercholesterolemia treatments on cardiovascular outcomes	252	27.38% (44.59%)	48.81% (49.99%)	+78.27%*	54	16.67% (37.27%)	55.56% (49.69%)	+233.29%*
Discuss current guidelines and recommendations for the management of hyperlipidemia in high - risk patients	354	28.06% (31.70%)	56.87% (34.56%)	+102.67%*	76	41.01% (31.23%)	68.86% (28.53%)	+67.91%*
Incorporate current data into secondary prevention treatment strategies for patients with the highest cardiovascular risk	345	35.07% (39.77%)	68.41% (38.47%)	+95.07%*	74	51.35% (41.08%)	76.35% (35.09%)	+48.69%*
Recognize barriers to access for PCSK9 monoclonal antibody therapy and discuss strategies to overcome them	288	43.75% (49.61%)	85.76% (34.94%)	+96.02%*	58	46.55% (49.88%)	82.76% (37.77%)	+77.79%*

- Both nurse practitioners and physicians demonstrated substantial and significant improvements, from Pre- to Post-Test, on all curriculum Learning Objectives
- Physicians achieved higher Post-Test scores, from much lower Pre-Test scores, compared to nurse practitioners, on findings from recent trials on PCSK9i therapy
- Nurse practitioners achieved greater gains from much lower Post-Test scores on incorporating current data into secondary prevention treatment strategies, compared to physicians

Cohort Comparison by Profession: Learning Domains

Learning Domain	Nurse Practitioners				Physicians			
	N	Pre-Test	Post-Test	% Change	*N*	Pre-Test	Post-Test	% Change
Knowledge	333	28.08% (30.48%)	54.75% (34.17%)	+94.98%*	70	30.00% (29.89%)	63.10% (33.08%)	+110.33%*
Competence	345	35.07% (39.77%)	68.41% (38.47%)	+95.07%*	74	51.35% (41.08%)	76.35% (35.09%)	+48.69%*

- Both nurse practitioners and physicians achieved substantial and significant improvements in score on both Knowledge and Competence items, from Pre- to Post-Test
- Compared to physicians, nurse practitioners achieved substantially higher gains on case-based Competence items, but lower gains on Knowledge items, from Pre- to Post-Test
- For both groups, lower scores at Pre- and Post-Test were measured on Knowledge items, compared to Competence

Identified Learning Gap, 1 of 2:
Guidelines for management of risk associated with statin and PCSK9i therapy

On two Knowledge questions on the risk of cardiovascular events associated with PCSK9 inhibitor and statin therapies, learners struggled to answer correctly at Post-Test.

Knowledge: In the FOURIER and ODYSSEY outcomes trials, what was the relative reduction in risk for major cardiovascular events with PCSK9 inhibitors compared to placebo?

Results:

- At Post-Test, 47% of learners correctly answered: “15%”

Knowledge: According to the 2018 Blood Cholesterol guidelines, for patients in which category of estimated 10-year ASCVD risk should risk enhancers be considered when discussing potential statin therapy for primary prevention?

Results:

- At Post-Test, 35% of learners correctly answered: “5% to 20%”

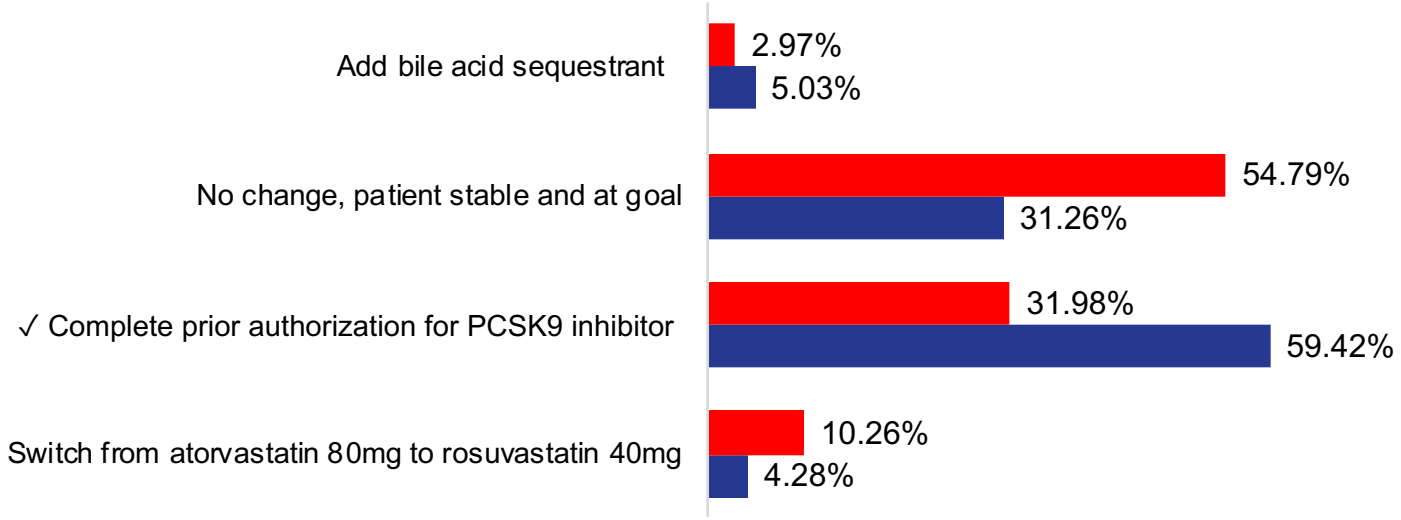
Identified Learning Gap, 2 of 2:
When to modify therapy from statin to PCSK9i

On a Competence item presenting the case of a patient receiving statin therapy, learners struggled at Post-Test to identify the need to begin the process of switching to PCSK9 inhibitor therapy.

Competence: A 67-year-old man with a history of NSTEMI (2 years and 6 months ago), hypertension, and dyslipidemia presents for a checkup. He is feeling well. LDL-C is 73 mg/dL. Meds: atorvastatin 80 mg qd, ezetimibe 10mg qd, metoprolol tartrate 100 mg bid, lisinopril 20 mg qd, and aspirin 81 mg qd. According to the 2018 Blood Cholesterol guidelines, which of the following is most appropriate?

Results:

- At Post-Test, 59% of learners correctly answered: “Complete prior authorization for PCSK9 inhibitor”

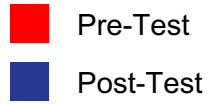


Overall Educational Impact

- Substantial and significant increases in score from Pre- to Post-Test were measured in both Knowledge and Competence
  - These gains were uniformly achieved on all curriculum Knowledge and Competence items, with gains seen between 72% and 115%
  - Improvements were very well retained, with minimal changes in score between Post-Test and PCA observed across Knowledge and Competence items
  - Significant increases on all curriculum Learning Objectives were also measured from Pre-Test to Post-Test
    - These improvements were also significant for nurse practitioners and for physicians
  - Final scores on Confidence and practice strategy questions were moderate (3.82 and 3.58)
- The analysis of scored items in the curriculum identified two **persistent learning gaps related to guidelines for management of risk associated with statin and PCSK9i therapy and when to modify therapy from statin to PCSK9i**
  - On two Knowledge items on the risk of cardiovascular events associated with PCSK9i and statin therapies, learners struggled to correctly identify level of risk at Post-Test
  - On a Competence item presenting the case of a patient receiving statin therapy, learners struggled at Post-Test to identify the need to begin the process of switching to PCSK9i therapy

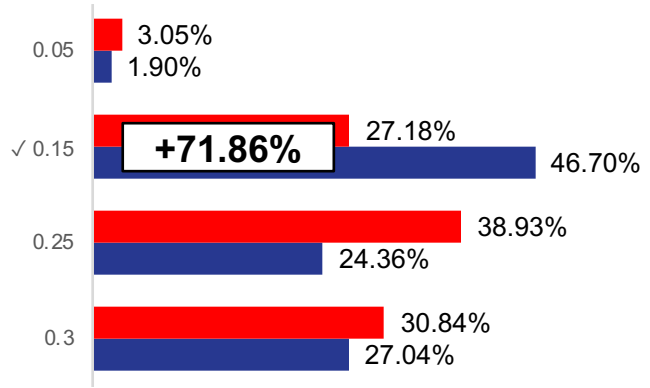
Appendix

Knowledge Items



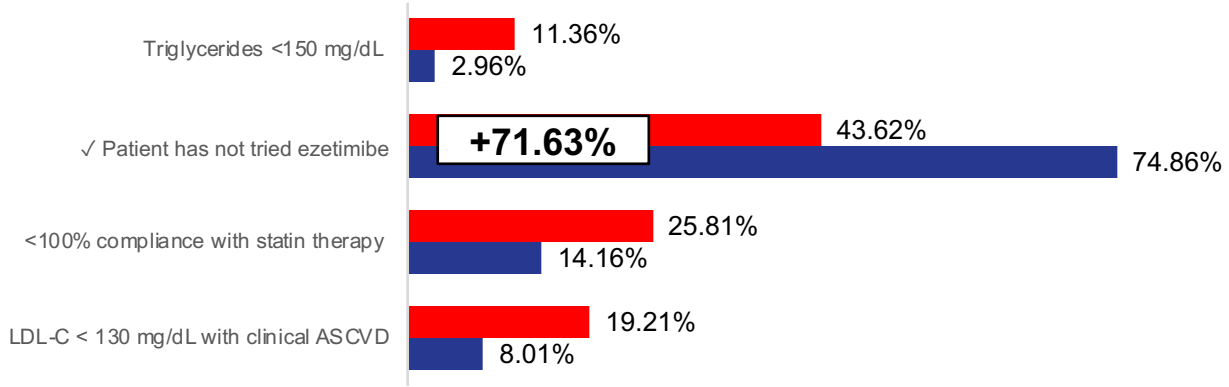
In the FOURIER and ODYSSEY outcomes trials, what was the relative reduction in risk for major cardiovascular events with PCSK9 inhibitors compared to placebo?

N = 655 – 895



Which of the following is a common barrier to prior authorization of PCSK9 inhibitor prescription?

N = 713 – 911

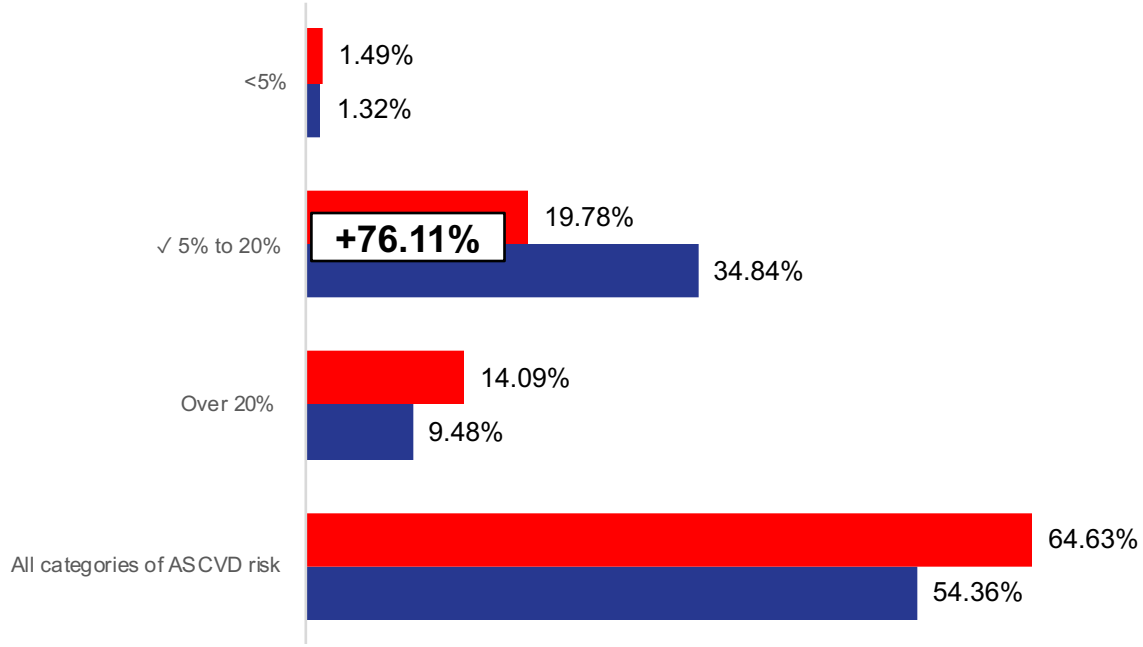


Note: data are matched.
Correct answer is designated by a ✓.

Knowledge Items

According to the 2018 Blood Cholesterol guidelines, for patients in which category of estimated 10-year ASCVD risk should risk enhancers be considered when discussing potential statin therapy for primary prevention?

N = 738 – 907

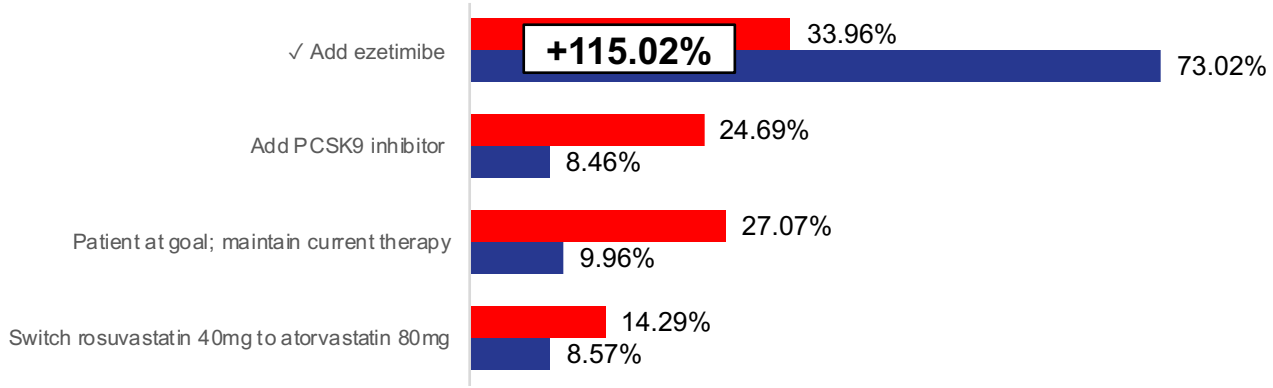


Note: data are matched.
Correct answer is designated by a ✓.

Competence Items

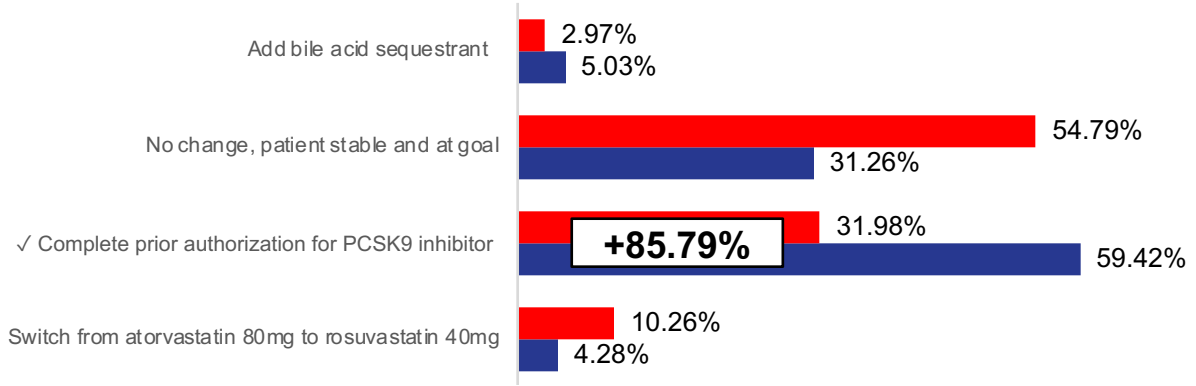
A 68-year-old woman with a history of NSTEMI (6 months ago), hypertension, dyslipidemia, and previous PCI, presents for a checkup. Her LDL-C is 89 mg/dL, HDL-C 52 mg/dL, and triglycerides 160 mg/dL. Current lipid-lowering therapy is rosuvastatin 40 mg qd. According to the 2018 Blood Cholesterol guidelines, what would be the next most appropriate step to take?

N = 798 – 934



A 67-year-old man with a history of NSTEMI (2 years and 6 months ago), hypertension, and dyslipidemia presents for a checkup. He is feeling well. LDL-C is 73 mg/dL. Meds: atorvastatin 80 mg qd, ezetimibe 10mg qd, metoprolol tartrate 100 mg bid, lisinopril 20 mg qd, and aspirin 81 mg qd. According to the 2018 Blood Cholesterol guidelines, which of the following is most appropriate?

N = 741 – 934



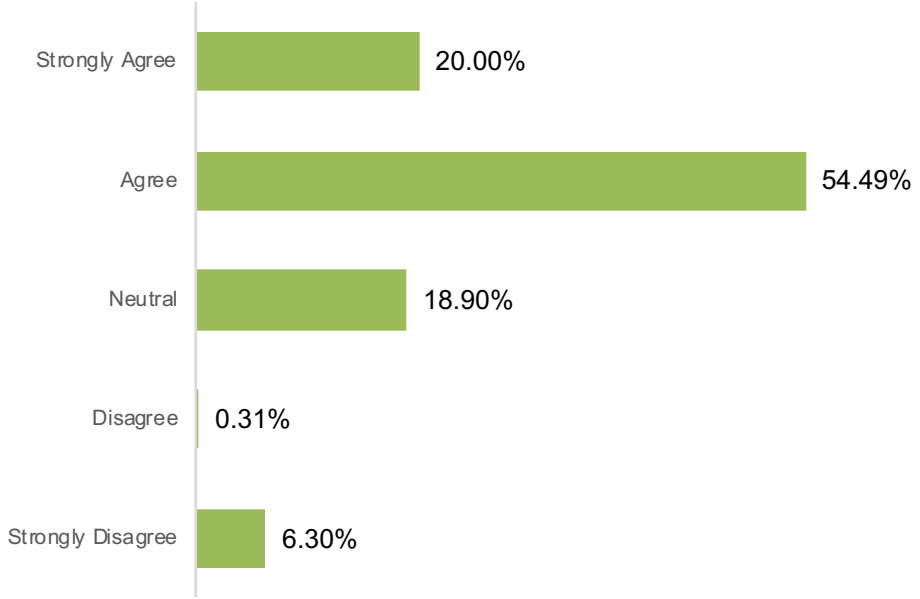
Note: data are matched.
Correct answer is designated by a ✓.

PCA

Confidence Item (given at 4 week follow-up)

Please rate your level of agreement with the following statement: “I am more confident in understanding how to apply 2018 Blood Cholesterol guidelines when managing patients at high risk for ASCVD."

N = 635

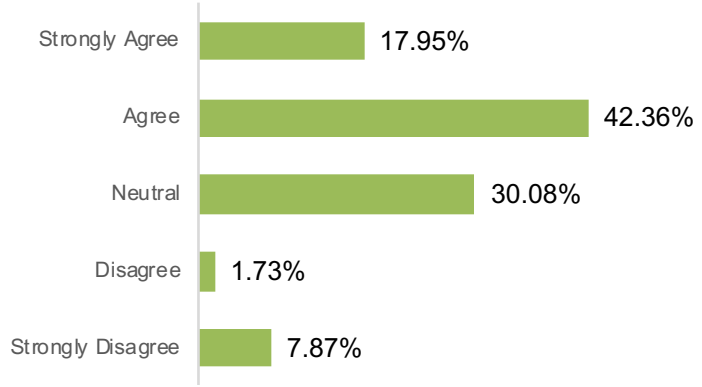


Practice Strategy Items (given at 4 week follow-up)

PCA

Please rate your level of agreement with the following statement: "I have increased use of maximally tolerated statin therapy and ezetimibe for secondary prevention in very high-risk patients."

N = 635



Please rate your level of agreement with the following statement: "I have significantly increased my attention to thorough documentation when submitting prior authorization for PCSK9 inhibitors."

N = 635