NACE *Conversations* in Primary Care 2019

Final Live Outcomes Report

Secondary Cardiovascular Risk Reduction: Incorporating Evolving Data to Individualize Care

Sanofi US and Regeneron Pharmaceuticals • IME-2018-13201

September 26, 2019

RealCME

ABC Association of Black Cardiologists, Inc. *Saving the Hearts and Minds of a Diverse America*

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NACE *Conversations* in Primary Care 2019

Secondary Cardiovascular Risk Reduction: Incorporating Evolving Data to Individualize Care

ABC Association of Black Cardiologists, Inc. Saving the Hearts and Minds of a Diverse America

2,012 Participants

3 Activities

1400 certificates issued to date

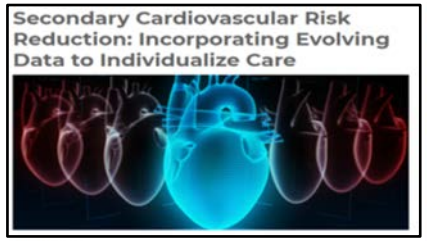
This education has the potential to impact **1,428,118** patients with hyperlipidemia on an annual basis.

24,717–30,210 Patients Weekly

2019 Conversations Activity	Date	Participants
Conversations In Primary Care 2019 Episode 1	2/9/2019	867
Conversations In Primary Care 2019 Episode 3	3/30/19	723
Conversations In Primary Care 2019 Episode 4	5/18/19	422
Live Guarantee:1500	**Total**	**2,012**

Speaker

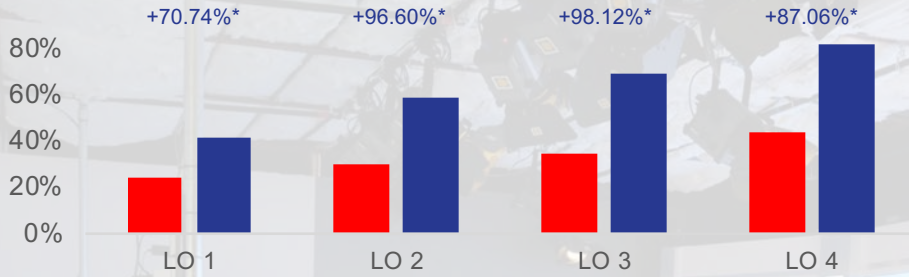
Karol Watson, MD, PhD
Professor of Medicine/Cardiology
Co-director, UCLA Program in Preventive Cardiology
Director, UCLA Barbra Streisand Women's Heart Health Program
David Geffen School of Medicine at UCLA
John Mazziotta, M.D., Ph.D. Term Chair in Medicine.



COURSE SUMMARY

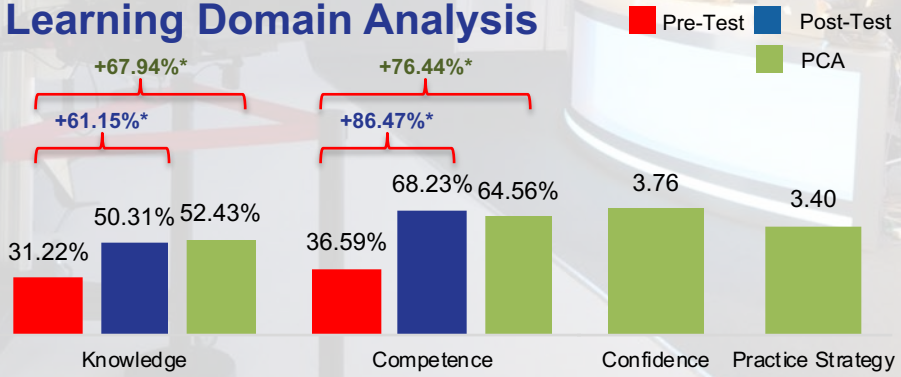
Cost: Free
Start Date: 02/19/2019
Expiration Date: 02/18/2020
Target Audience: Primary Care Physicians, Nurse Practitioners, Physicians Assistants
Format: Webcast
Estimated Time To Complete CME Activity: 1 hour
Credit(s): 1.0 *AMA PRA Category 1 Credit™* 1.0 AANP Contact hour including 0.75 pharmacology hours
Hardware/Software Requirements: Any web browser

Learning Gains Across Objectives



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

Learning Domain Analysis



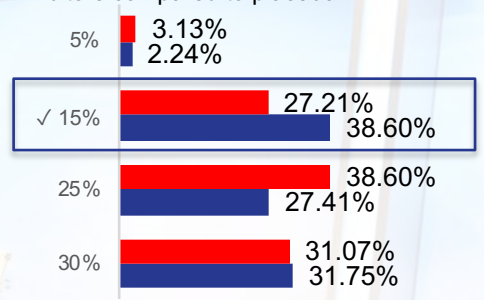
- Learners demonstrated strong improvements from Pre- to Post-Test and PCA in Knowledge and Competence though Post-Test scores remained low. Scores continued to increase between Post-Test and PCA in Knowledge
- In Confidence and Practice Strategy, which were measured at 4 week follow-up only, learners reported greater confidence in understanding how to apply 2018 Blood Cholesterol guidelines when managing patients at high risk for ASCVD, increased use of maximally tolerated statin therapy and ezetimibe for secondary prevention in very high-risk patients, and increased attention to thorough documentation when submitting prior authorization for PCSK9 inhibitors, though there are opportunities for further education in these areas.

Persistent Learning Gaps/Needs

Risks reduction demonstrated with PCSK9 inhibitors, and estimating Cardiovascular Risk

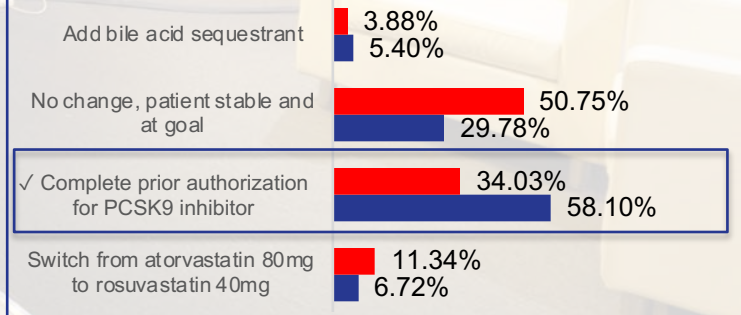
On two Knowledge items asking learners to quantify the risks associated with PCSK9 inhibitor and statin therapies, learners scored low at Post-Test.

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



Advancing Therapy for Patients with the Highest Cardiovascular Risk

On a Competence item presenting the case of a patient with a history of NSTEMI, taking atorvastatin and ezetimibe with an LDL-C of 73 mg/dL, learners struggled to identify adding a PCSK9 inhibitor as the most appropriate next step.



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IME-2018-13201

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Curriculum Patient Impact

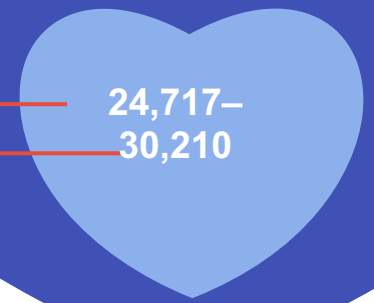
In the evaluation, learners (N = 740) were asked to report how many patients with hyperlipidemia they see in any clinical setting per week by selecting a range. The resulting distribution of learner responses was then extrapolated to reflect the total number of learners who have attended the onsite and online meetings.

The findings reveal that this education has the potential to impact

1,428,118

patients with hyperlipidemia on an annual basis.

24,717–30,210 patients on a weekly basis



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Co-director, UCLA Program in Preventive Cardiology
Director, UCLA Barbra Streisand Women's Heart Health Program
Los Angeles, CA

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Charlotte, NC

2019 Commercial Support

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

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

Curriculum Overview

Three Live Virtual CME Symposia

Enduring CME Symposium Webcast

https://www.naceonline.com/courses/secondary-cardiovascular-risk-reduction-incorporating-evolving-data-to-individualize-care-1

Secondary Cardiovascular Risk Reduction: Incorporating Evolving Data to Individualize Care

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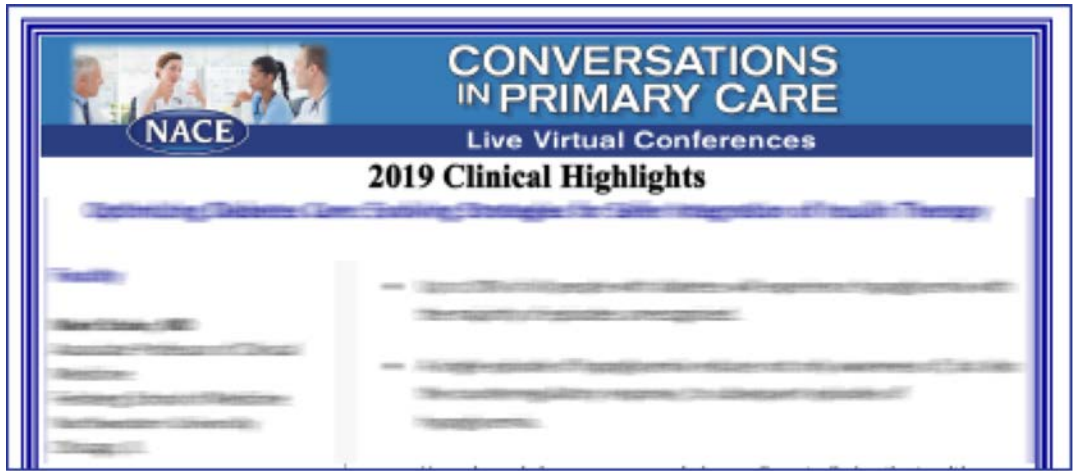
Hardware/Software Requirements: Any web browser

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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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

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Level 1
Participation
Demographics
Patient Reach

Participation

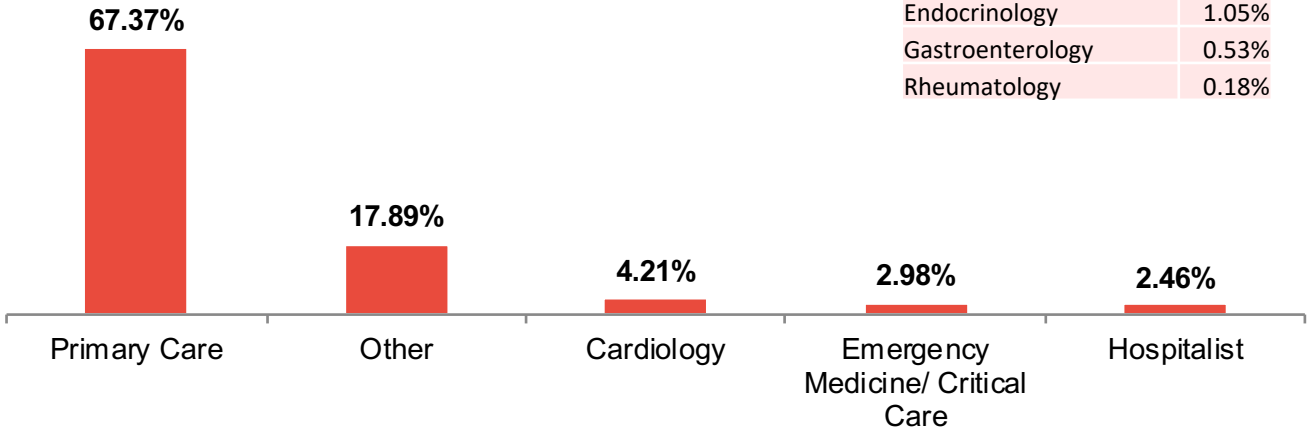
2,012
Total Attendees

3 Activities

Level 1: Demographics and Patient Reach

N = 792

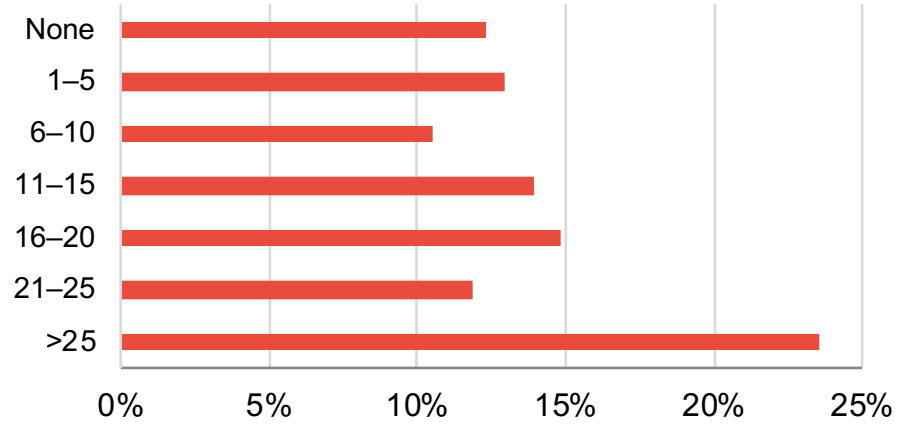
Specialty



Under 2%	
Neurology/Psychiatry	1.75%
Pulmonology	1.58%
Endocrinology	1.05%
Gastroenterology	0.53%
Rheumatology	0.18%

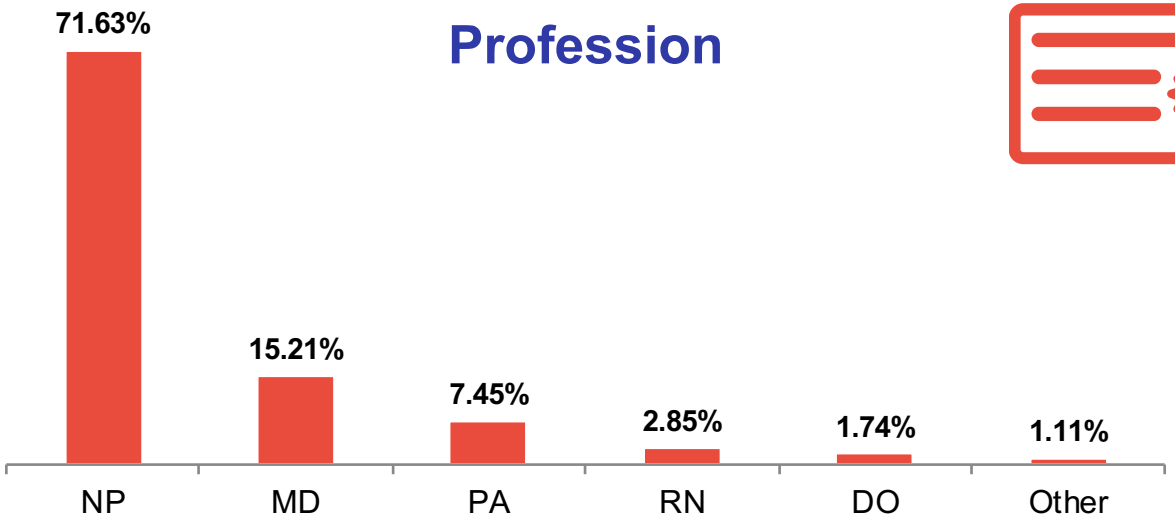
Patient Care Focus: 91%

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

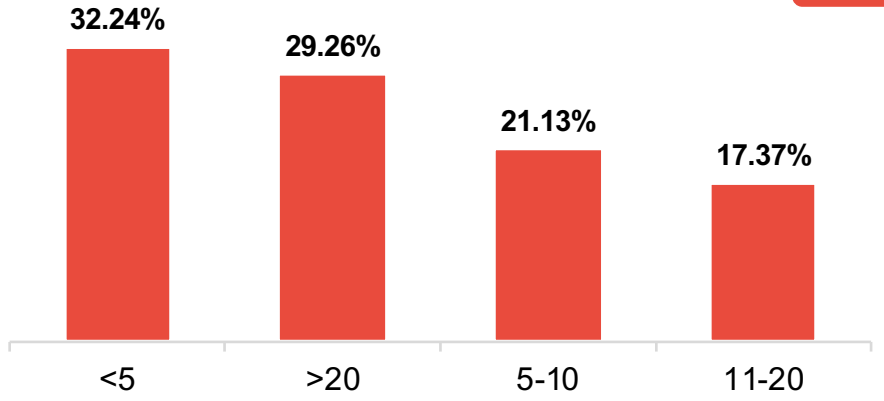


Average number of patients with hyperlipidemia seen each week per clinician: 15

Profession



Years in Practice



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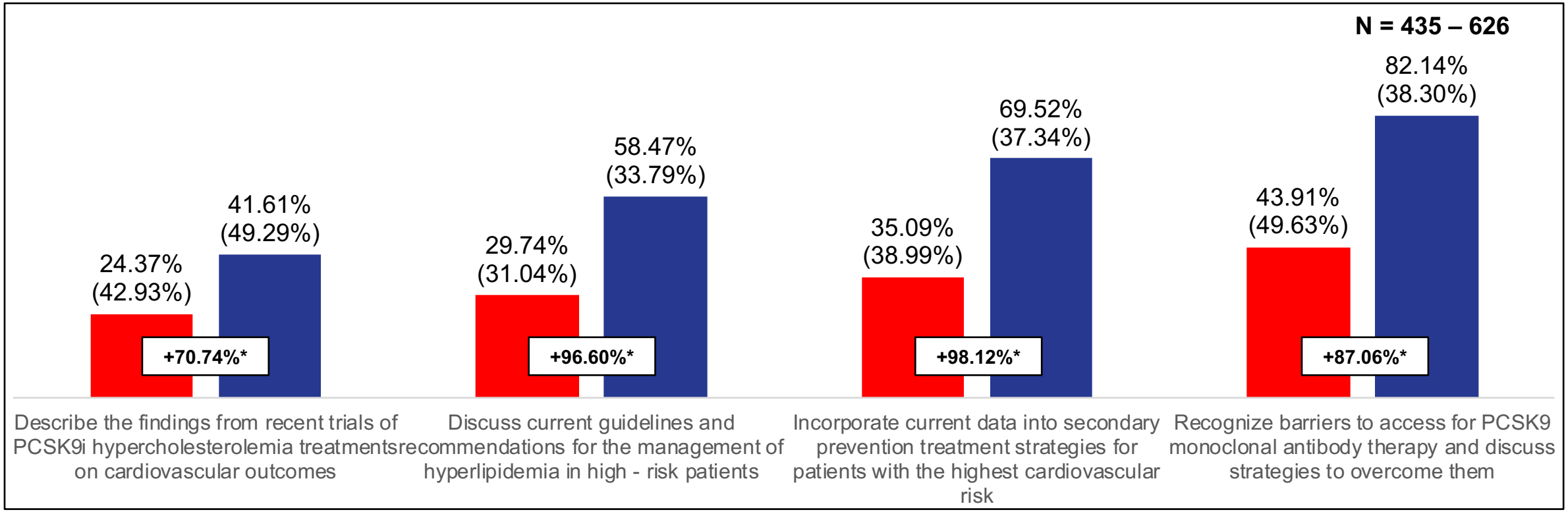
Level 2-5:
Outcomes Metrics

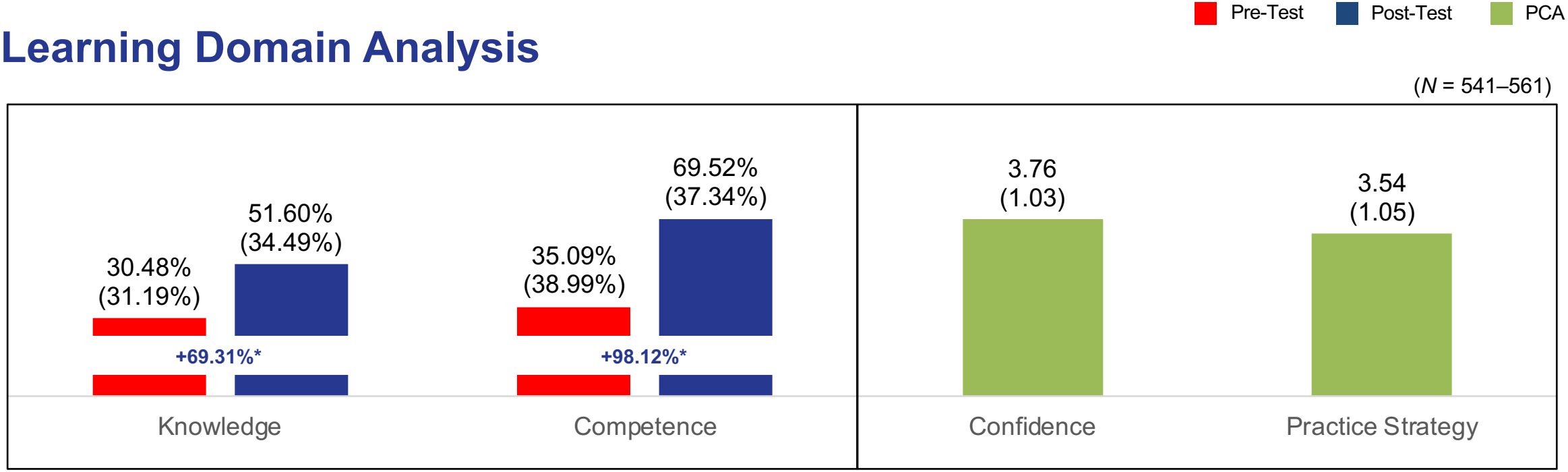
Learning Objectives Analysis



- Substantial and significant improvements were measured on all curriculum Learning Objectives, from low (< 44%) scores at Pre-Test
- The highest Post-Test scores were on items related to barriers to access for PCSK9 therapy, driven by a Knowledge item asking learners to identify the most common barrier to access

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

Learning Domain Analysis

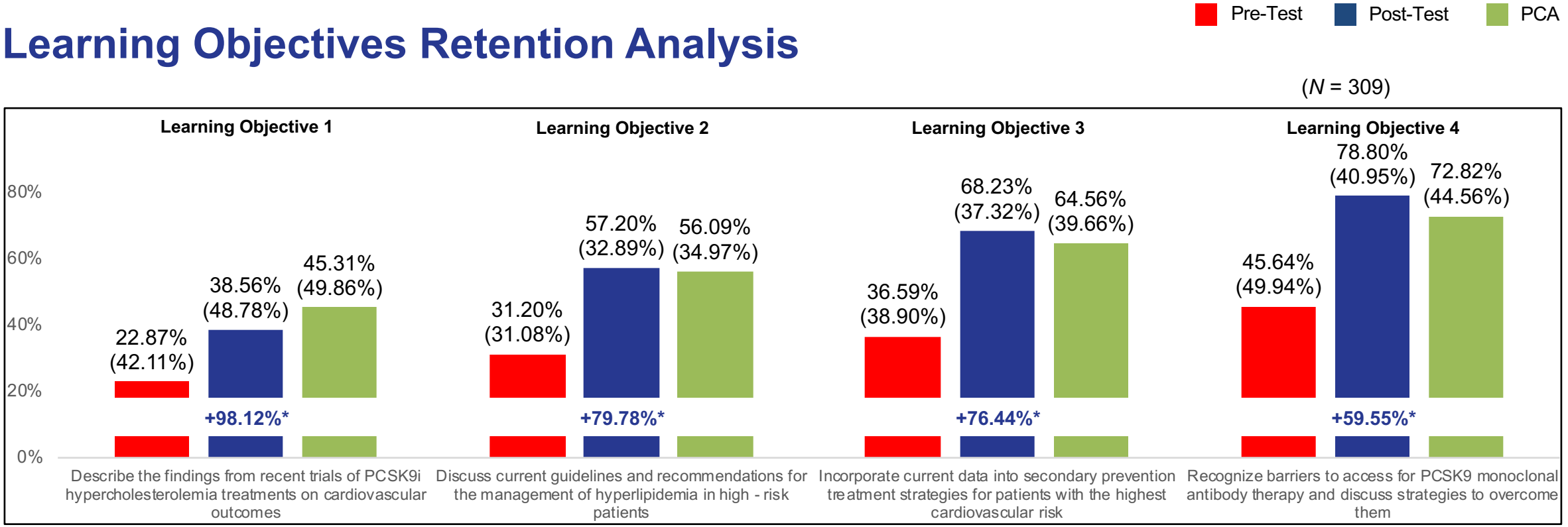


- Learners demonstrated strong improvements from Pre- to Post-Test in Knowledge and Competence
- In spite of this, Post-Test scores in both Knowledge and Competence remained low (52% and 70%), following low Pre-Test scores (30% and 35%)
- In Confidence and Practice Strategy, which were measured at 4 week follow-up only, moderate scores were observed. Learners reported greater confidence in understanding how to apply 2018 Blood Cholesterol guidelines when managing patients at high risk for ASCVD, increased use of maximally tolerated statin therapy and ezetimibe for secondary prevention in very high-risk patients, and increased attention to thorough documentation when submitting prior authorization for PCSK9 inhibitors, though there are opportunities for further education in these areas.

Note: Knowledge and Competence data 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***

Learning Objectives Retention Analysis

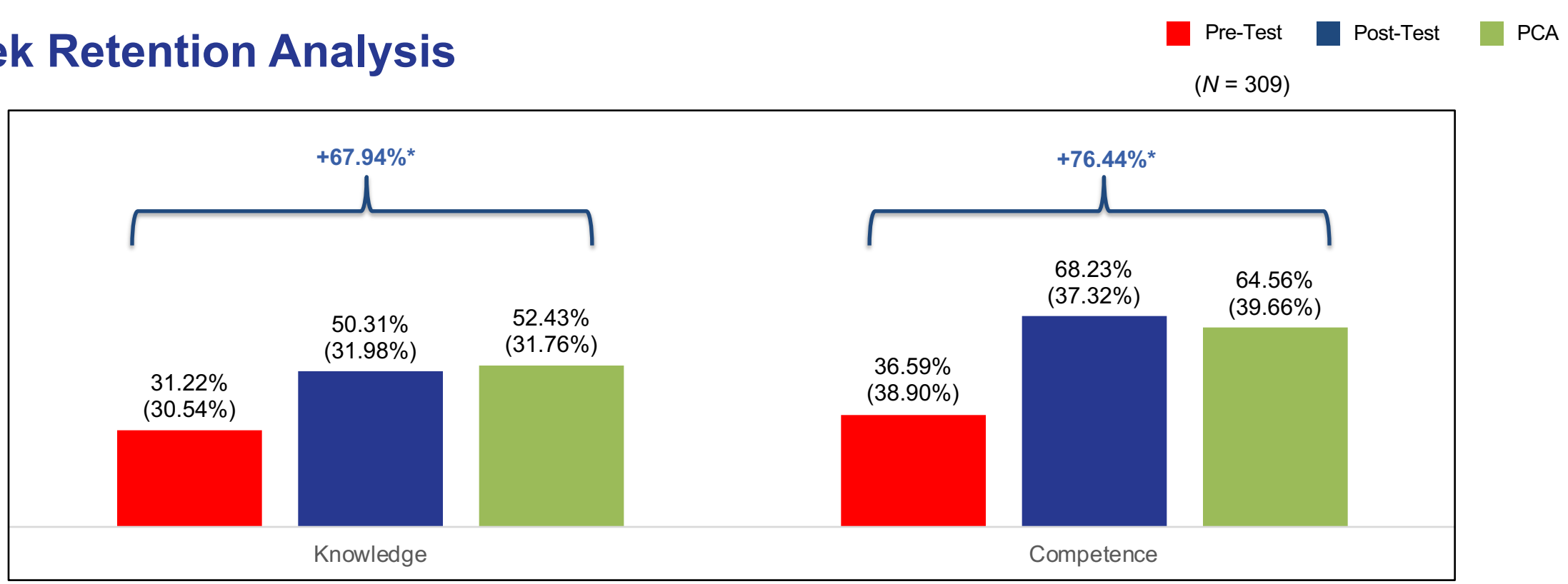


- Substantial and significant gains, ranging from 76% to 98%, were retained across all four curriculum learning objectives, from Pre-Test to the PCA
- On the Learning Objective concerning recent findings from PCSK9i treatments, gains were measured from Post-Test to PCA; on the other three, some slippage in score was observed
- PCA scores the learning objective related to barriers to access for PCSK9 therapy were highest, due to strong scores on a knowledge question asking about common barriers

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



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 also asked at Pre- and Post-Test
- A statistically significant net gain was measured from Pre-Test to the Post Curriculum Assessment (PCA) in both Knowledge (68%) and Competence (76%)
- In both Knowledge, some further increase in score from Post-Test to PCA was measured, driven by high scores at PCA on a question concerning barriers to access for PCSK9i therapy

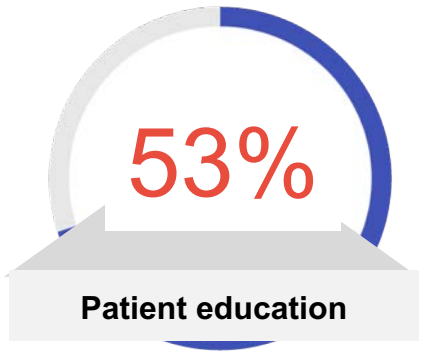
Note: data is matched; learners with a score for the given domain on both the Pre-Test and PCA are included

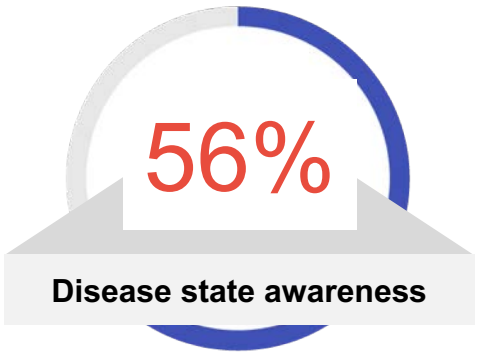
***significant at the p ≤ 0.05 level**

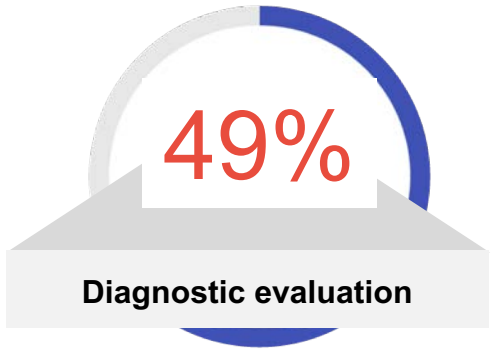
(4-week Post Assessment)

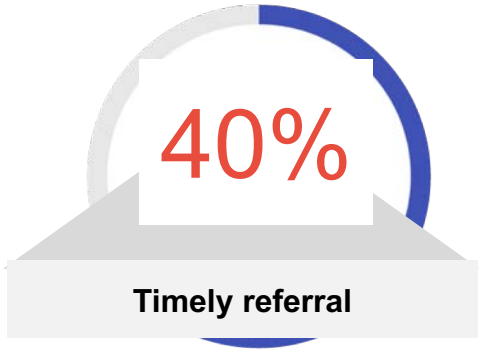
Please select the specific areas of *skills, or practice behaviors*, you have improved regarding the treatment of patients with hyperlipidemia since this CME activity. (Select all that apply.)

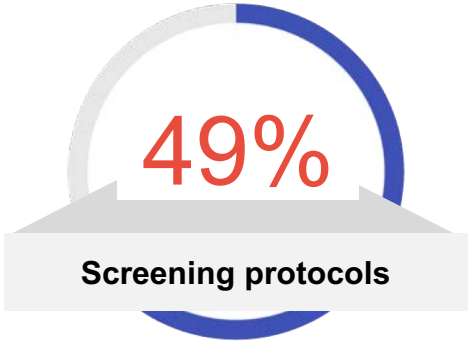
N=559

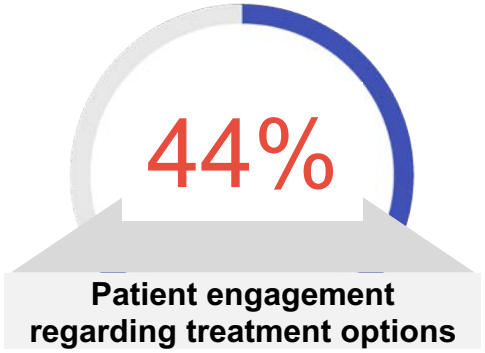








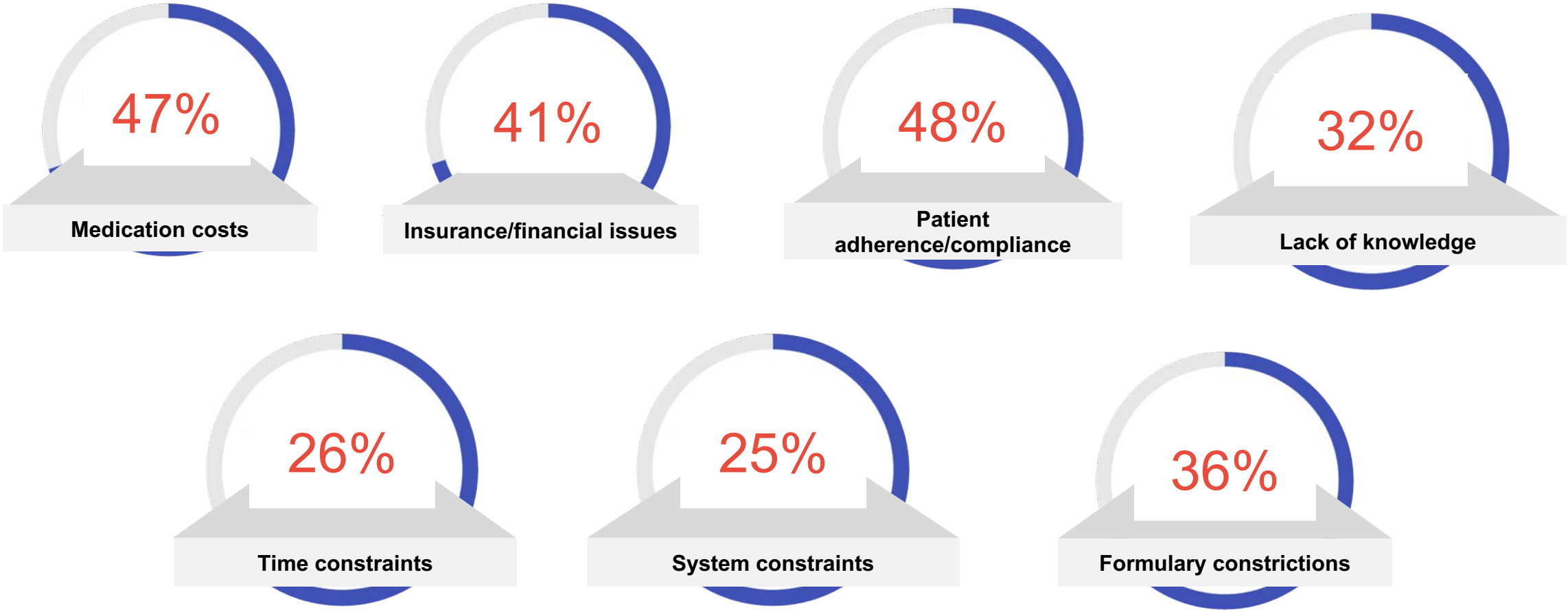




(4-week Post Assessment)

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=559



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	210	24.76% (43.16%)	41.90% (49.34%)	**+69.22%***	50	16.00% (36.66%)	44.00% (49.64%)	**+175.00%***
Discuss current guidelines and recommendations for the management of hyperlipidemia in high - risk patients	292	29.91% (31.24%)	57.13% (34.26%)	**+91.01%***	74	40.77% (30.16%)	64.86% (29.71%)	**+59.09%***
Incorporate current data into secondary prevention treatment strategies for patients with the highest cardiovascular risk	284	36.44% (38.93%)	68.13% (37.49%)	**+86.96%***	72	53.47% (40.25%)	75.69% (33.33%)	**+41.56%***
Recognize barriers to access for PCSK9 monoclonal antibody therapy and discuss strategies to overcome them	233	46.78% (49.90%)	87.98% (32.52%)	**+88.07%***	55	40.00% (48.99%)	78.18% (41.30%)	**+95.45%***

- Nurse practitioners and physicians both demonstrated substantial and significant improvements across all curriculum Learning Objectives
- Physicians had higher Post-Test scores on all curriculum Learning Objectives except the Objective related to barriers to access for PCSK9 therapy

Cohort Comparison by Profession: Learning Domains

Learning Domain	Nurse Practitioners				Physicians			
	N	Pre-Test	Post-Test	% Change	*N*	Pre-Test	Post-Test	% Change
Knowledge	269.0	29.49% (29.90%)	54.03% (33.14%)	**+83.21%***	68.0	27.94% (30.58%)	54.66% (35.22%)	**+95.63%***
Competence	284.0	36.44% (38.93%)	68.13% (37.49%)	**+86.96%***	72.0	53.47% (40.25%)	75.69% (33.33%)	**+41.56%***

- Nurse Practitioners and Physicians both demonstrated substantial and significant improvements in both Knowledge and Competence
- Physicians had higher Post-Test scores on Competence items, and similar scores on Knowledge items, compared to nurse practitioners

Identified Learning Gap, 1 and 2 of 3:

Risks reduction for MACE demonstrated with PCSK9 inhibitors, and use of Risk Enhancers for estimating cardiovascular risk

On two Knowledge items asking learners about cardiovascular risk reduction demonstrated in PSCK9-inhibitor outcome trials, and how to use risk enhancers when assessing need for statin therapy in primary prevention, learners scored low 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, 39% 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, 34% of learners correctly answered: “5% to 20%”

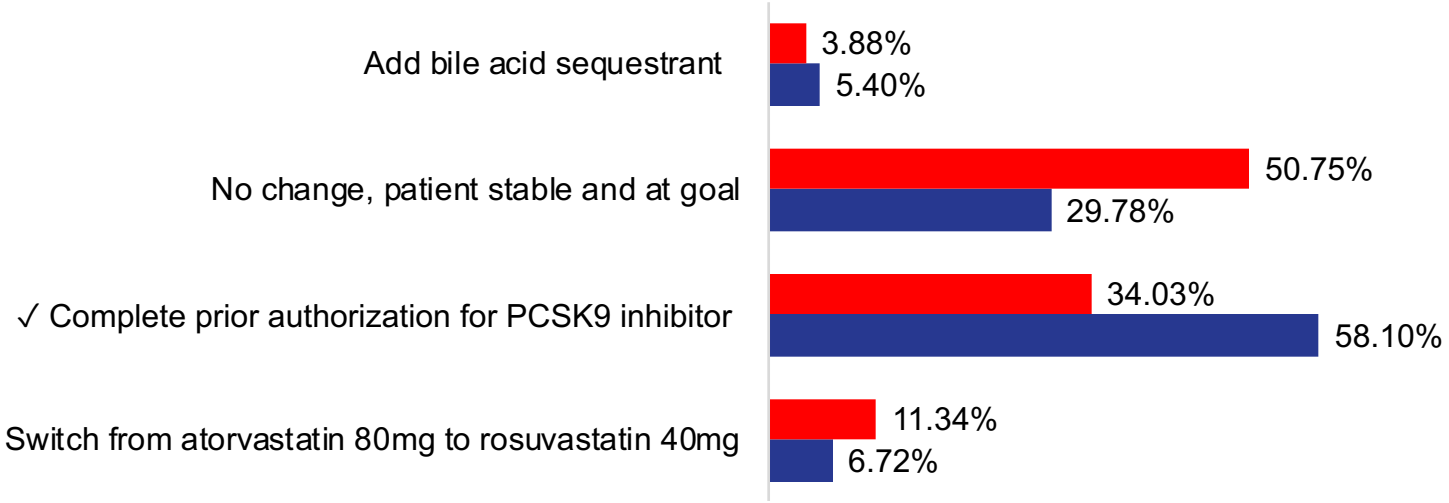
Identified Learning Gap, 2 of 3:
Advancing therapy for patients with the highest cardiovascular risk

On a Competence item presenting the case of a patient with a history of NSTEMI, taking atorvastatin and ezetimibe with an LDL-C of 73mg/dL, learners struggled to identify that the patient was a candidate for PCSK9 inhibitor therapy and should proceed with prior authorization as the most appropriate next step.

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, 58% of learners correctly answered: “Complete prior authorization for PCSK9 inhibitor”



Overall Educational Impact

- Significant improvements (of 69% and 98%) were seen in both learner Knowledge and Competence, from Pre- to Post-Test
  - Low Post-Test scores (52%) were measured in Knowledge, with moderate (70%) Post-Test scores in Competence
    - The three curriculum Knowledge questions concerned the use of risk enhancers for primary prevention, MACE risk reduction demonstrated with PCSK9i therapy, and documentation requirements for access for PCSK9i therapy.
  - Final scores on Confidence and practice strategy questions, measured at 4 weeks, were moderate (3.76 and 3.54) but learners reported greater confidence in understanding how to apply 2018 Blood Cholesterol guidelines when managing patients at high risk for ASCVD, increased use of maximally tolerated statin therapy and ezetimibe for secondary prevention in very high-risk patients, and increased attention to thorough documentation when submitting prior authorization for PCSK9 inhibitors, though there are opportunities for further education in these areas.

Overall Educational Impact

- Substantial and significant improvements ranging from 71% to 98% were measured across all Learning Objectives, from Pre-Test to Post-Test. All Pre-Test scores were low (< 44%), and the highest Post-Test scores were achieved in recognizing barriers to access for PCSK9 therapy.
- The analysis of the Knowledge and Competence domains identified three persistent learning gaps related to Risks reduction for MACE demonstrated with PCSK9 inhibitors, use of Risk Enhancers for estimating cardiovascular risk, and Advancing Therapy for Patients with the Highest Cardiovascular Risk.
  - Pre- and Post-Test scores were low on two Knowledge items about identifying the risk reduction associated with PCSK9i therapy, and how to use risk enhancers to determine statin therapy for primary prevention.
  - On a Competence item presenting the case of a patient with a history of NSTEMI, taking atorvastatin and ezetimibe with an LDL-C of 73mg/dL, learners struggled to identify that the patient was a candidate for PCSK9 inhibitor therapy and should proceed with prior authorization as the most appropriate next step at Post-Test.

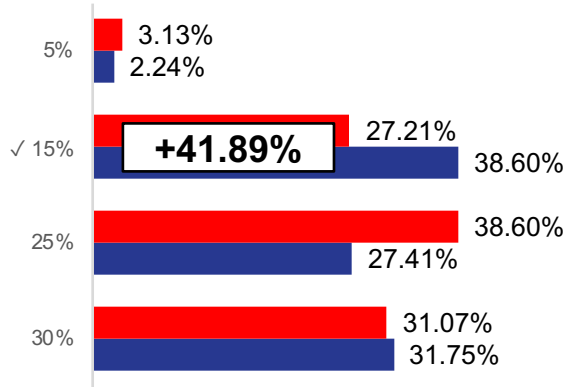
Appendix

Knowledge Items

Pre-Test
Post-Test

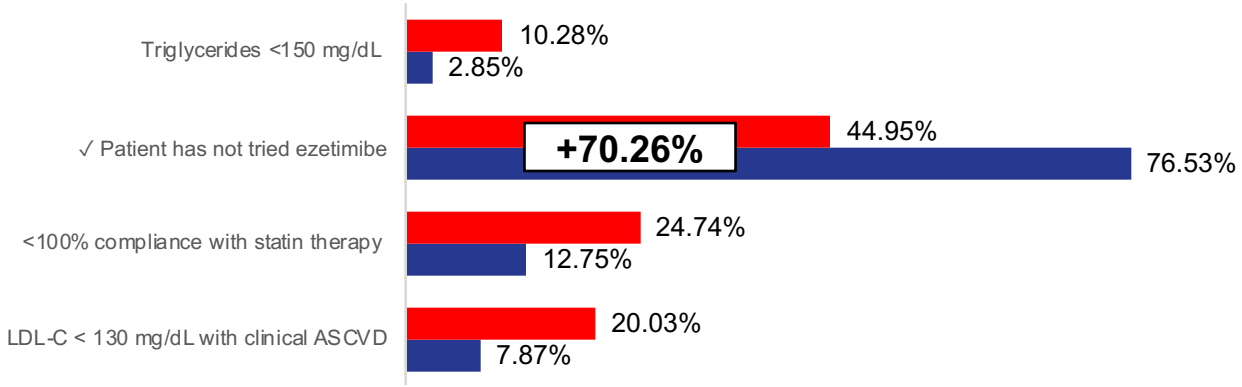
In the FOURIER and ODYSSEY outcomes trials, what was the relative reduction in risk for major cardiovascular events with PCSK9 inhibitors compared to placebo?

N = 544 – 715



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

N = 574 – 737

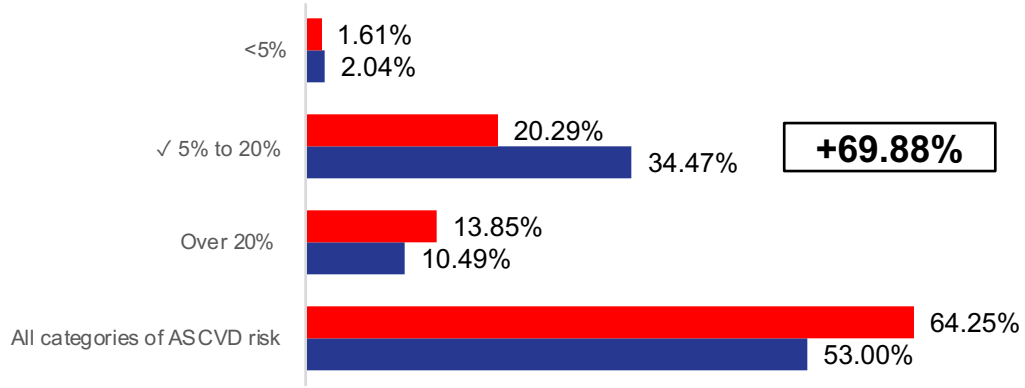


Knowledge Items

Pre-Test
Post-Test

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 = 621 – 734

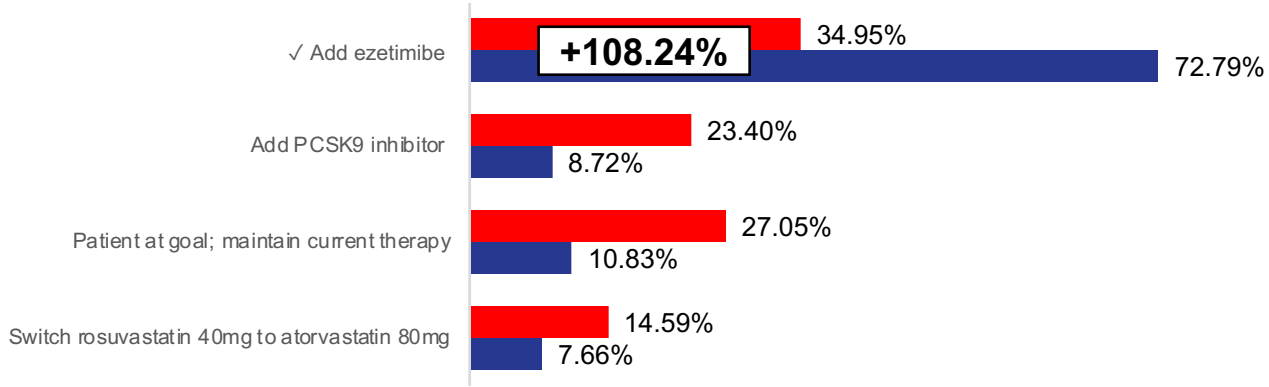


Competence Items

Pre-Test
Post-Test

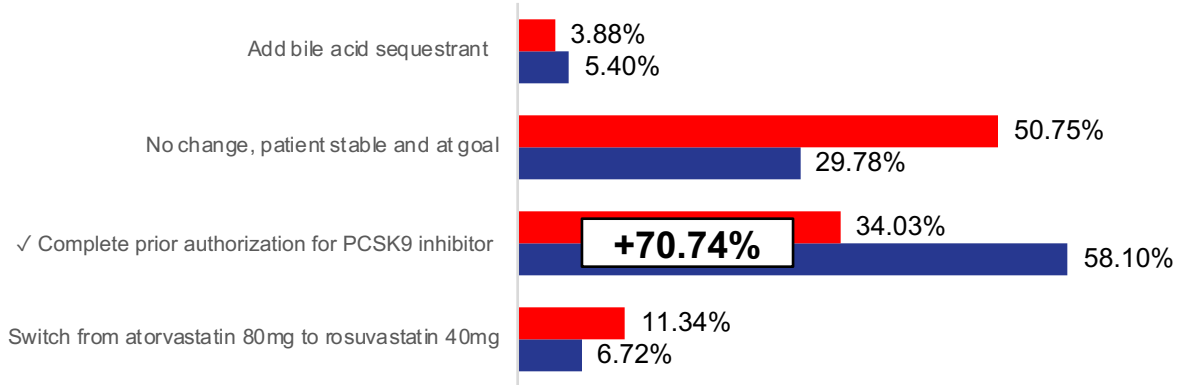
A 68-year-old woman with a history of NSTEMI (6 months ago), hypertension, dyslipidemia, and previous PCI, presents for a checkup. Her LDL-C is 89 mg/dL, HDL-C 52 mg/dL, and triglycerides 160 mg/dL. Current lipid-lowering therapy is rosuvastatin 40 mg qd. According to the 2018 Blood Cholesterol guidelines,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

N = 658 – 757



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 = 670 – 759

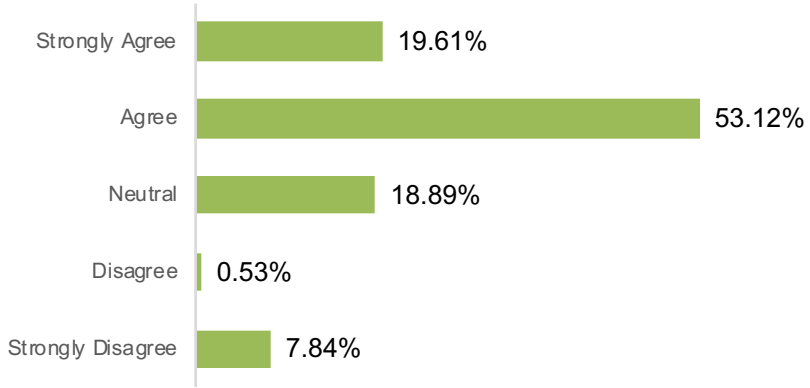


Confidence Item (given at 4 week follow-up)

PCA

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 = 561

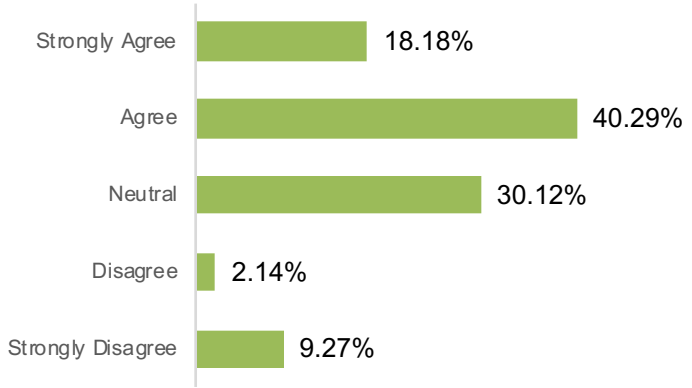


Practice Strategy Items (given at 4 week follow-up)

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 = 561



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 = 561