Emerging Challenges in Primary Care: 2020
Conversations in Primary Care: 2020

Improving Outcomes in Severe Hypercholesterolemia: It's a Team Effort

Kaneka Pharma America LLC

January 29, 2021

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Emerging Challenges in Primary Care and Conversations in Primary Care: 2020

This curriculum focused on identification and management of Familial Hypercholesterolemia (FH)

Participation

4,580
Total Attendees

4 Virtual Sessions

1969 certificates issued to date

This education has the potential to impact
10,479,040
Patients on an annual basis.

196,940 – 206,100
Patients Weekly

2020 Session	Date	Attendees
Conversations in Primary Care, Episode 4	5/16/20	2,412
Conversations Episode 4, Rebroadcast	5/23/20	587
Emerging Challenges in Primary Care, Episode 8 *Virtual: National audience*	6/27/20	1,323
Emerging Challenges Episode 8, Rebroadcast	7/11/20	258
Total		**4,580**

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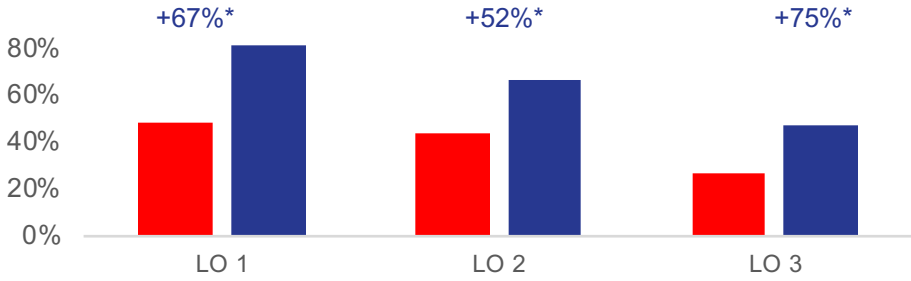
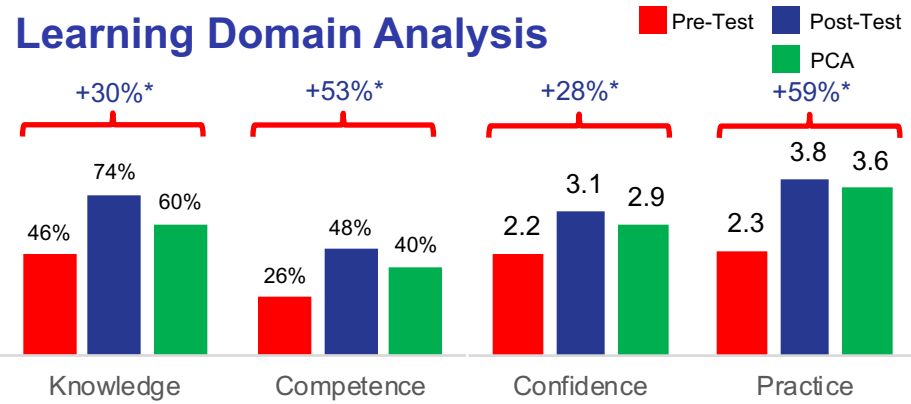
Learning Gains Across Objectives



- **LO 1, 67%* Improvement:** Define familial hypercholesterolemia (FH)
- **LO 2, 52%* Improvement:** Review the pathophysiology of, and clinical diagnosis of FH and its variants
- **LO 3, 75%* Improvement:** Incorporate currently available treatment options into the care of patients with FH

Learning Domain Analysis



- In each of the four curriculum learning domains, substantial and significant gains were achieved from Pre- to Post-Test
- While strongest improvements were measured in Competence, this domain also had lowest Pre- and Post-Test scores; low scores were seen on both an item addressing initiation of therapy and another on when to refer for lipoprotein apheresis
- Higher scores in Knowledge were driven by an item about the definition of familial hypercholesterolemia
- In practice strategy, strong improvements to moderate Post-Test average ratings were given on intent to consider genetic testing for FH among patients with LDL-C > 190 mg/dL
- Low to moderate Pre- and Post-Test Confidence may reflect learner awareness of outstanding gaps in proficiency in this area

Persistent Learning Gaps/Needs

Pathophysiology of FH

Learners remained challenged in recognizing the pathophysiologic mechanism underlying forms of FH.

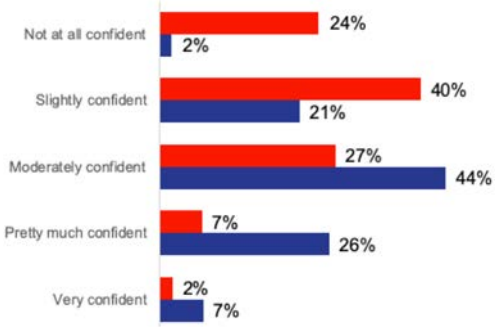
Selecting a high-intensity statin as first-line therapy for FH

Learners struggled to correctly identify the need to start a high-intensity statin in a patient with a family history including a death from MI and the monogenic LDL-R mutation associated with FH.

When to refer FH patients for lipoprotein apheresis

Learners remained challenged to correctly identify the need to refer for lipoprotein apheresis

Low baseline confidence levels to manage FH



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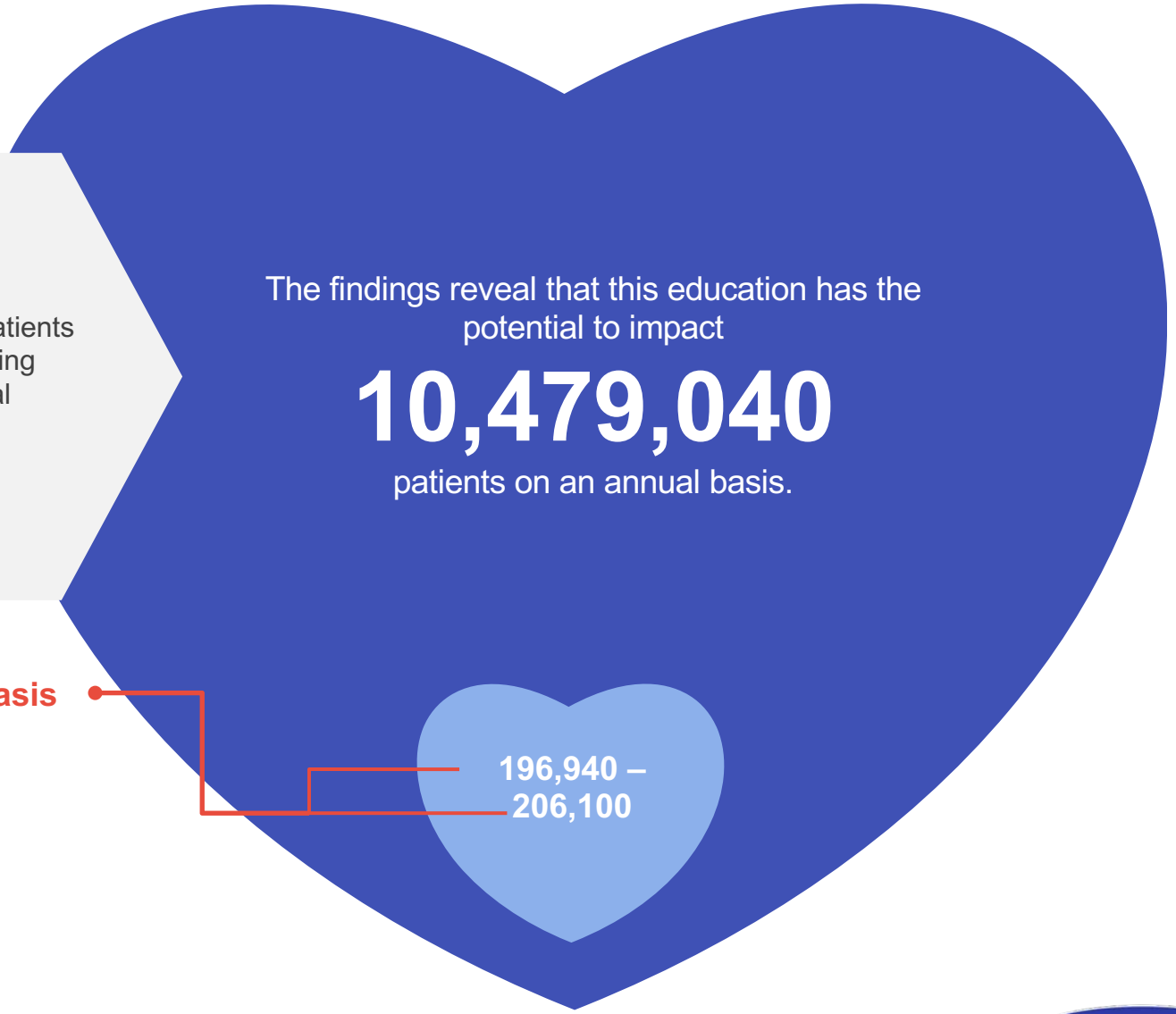
Curriculum Patient Impact

In the Post-Test, learners (N = 1,281) were asked to report how many patients they see per week in any clinical setting by selecting a range. The resulting distribution of learner responses was then extrapolated to reflect the total number of learners who have attended the sessions.



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Commercial Support

The Emerging Challenges in Primary Care: 2020 and Conversations in Primary Care: 2020 series of CME activities were supported through educational grants or donations from the following companies:

- Amgen
- Astellas Pharma Global Development, Inc.
- AstraZeneca Pharmaceuticals LP.
- Bayer Healthcare Pharmaceuticals Inc.
- Esperion Therapeutics, Inc.
- Ferring Pharmaceuticals, Inc.
- Gilead Sciences, Inc.
- Grifols
- Kaneka Pharma America LLC
- Lilly
- Novartis Pharmaceuticals Corporation
- Novo Nordisk, Inc.
- Takeda Pharmaceuticals U.S.A., Inc.

Overview

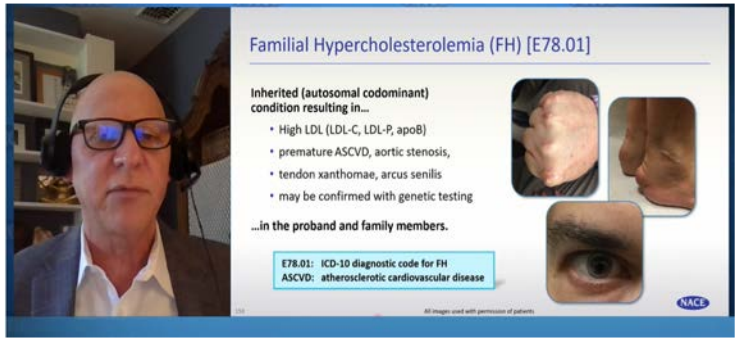
Learning Objectives

- Define familial hypercholesterolemia (FH)
- Review the pathophysiology and clinical diagnosis of FH and its variants
- Incorporate currently available treatment options into the care of patients with FH

Curriculum Overview

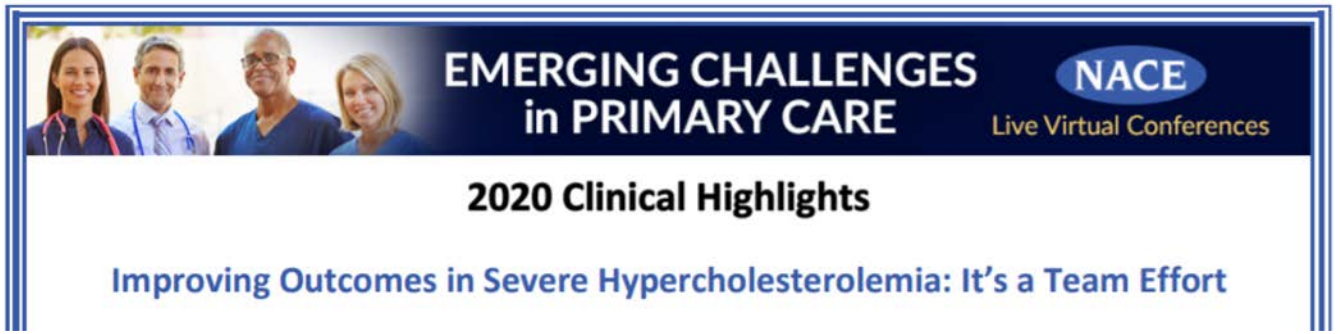
2 Accredited Live Virtual Symposia with

2 Rebroadcasts: May – July 2020



Clinical Highlights eMonograph

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



Enduring CME Symposium Webcast

Available at:
https://www.naceonline.com/courses/improving-outcomes-in-severe-hypercholesterolemia-its-a-team-effort

Improving Outcomes in Severe Hypercholesterolemia: It's a Team Effort

COURSE SUMMARY

Cost: Free

Start Date: 06/30/2020

Expiration Date: 06/29/2021

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*™
1.0 AANP Contact hour which includes 0.75 pharmacology hours

Hardware/Software Requirements: Any web browser

Speaker

Daniel Soffer, MD, FNLA, FACP
Internal Medicine/Preventive Cardiology
University of Pennsylvania Health System
PennCareMedia
Penn Medicine at Radnor
Perelman Center for Advanced Medicine
Philadelphia, PA

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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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Total		**4,580**

Level 1
Participation
Demographics
Patient Reach

Participation

4,580*
Total Attendees

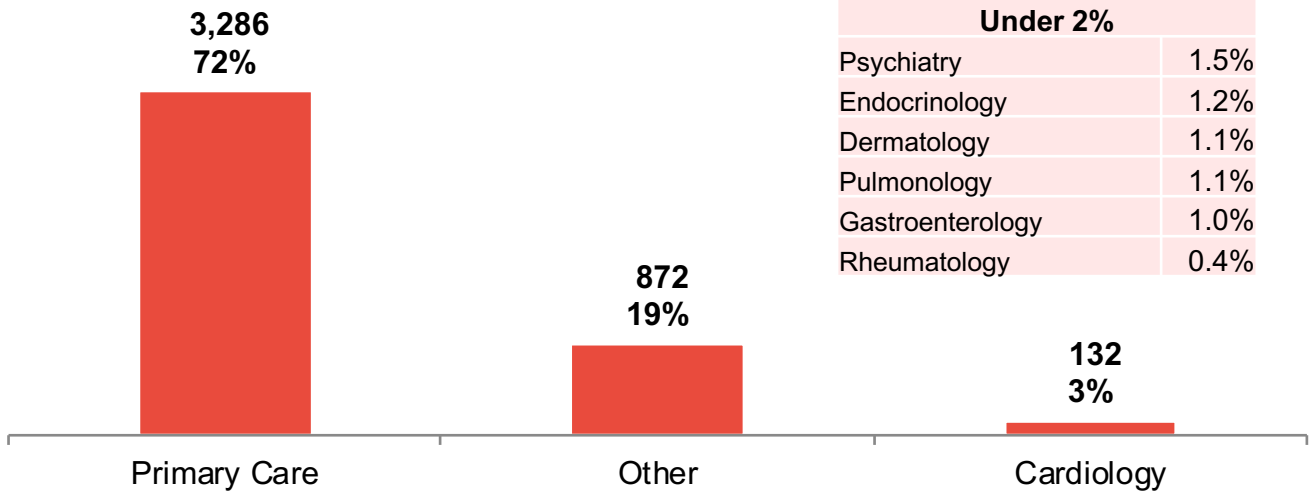
4 Virtual Sessions

1,459 Follow-up Participants
32% Rate of follow-up engagement

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

Level 1: Demographics and Patient Reach

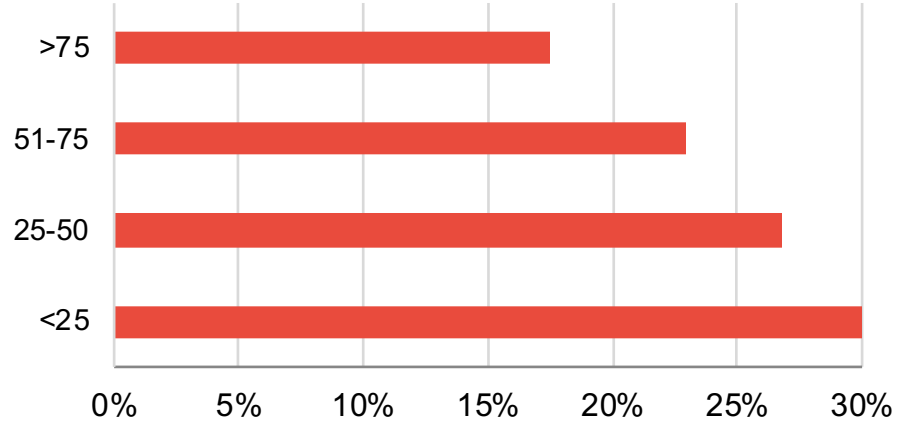
Specialty



Under 2%	
Psychiatry	1.5%
Endocrinology	1.2%
Dermatology	1.1%
Pulmonology	1.1%
Gastroenterology	1.0%
Rheumatology	0.4%

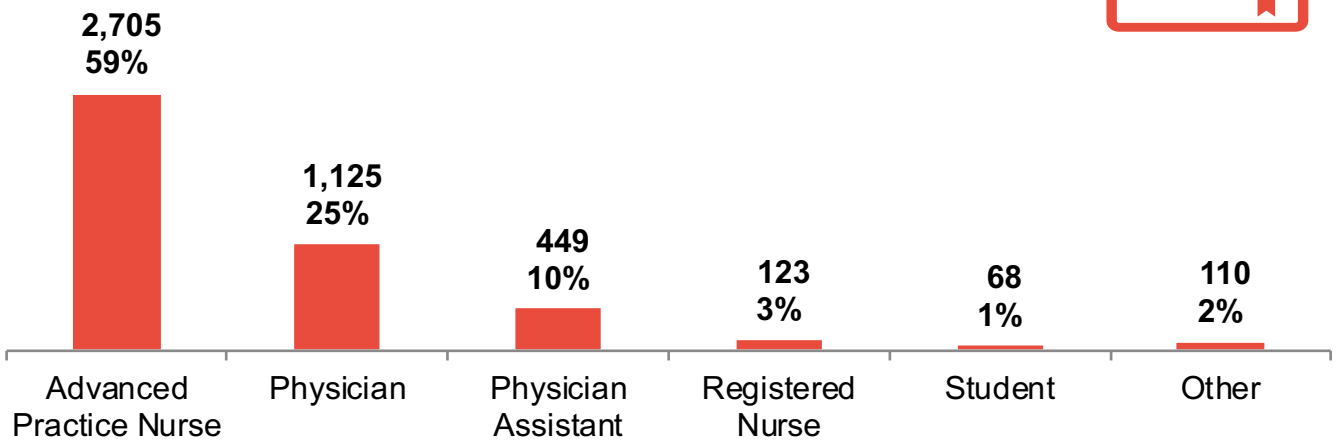
Patient Care Focus: 91%

Patients seen each week, in any clinical setting:

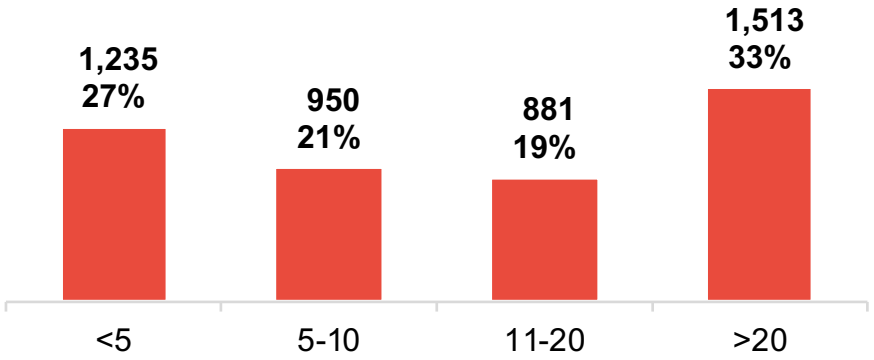


Average number of patients seen each week per clinician: 44

Profession



Years in Practice



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Level 2-5:
Outcomes Metrics

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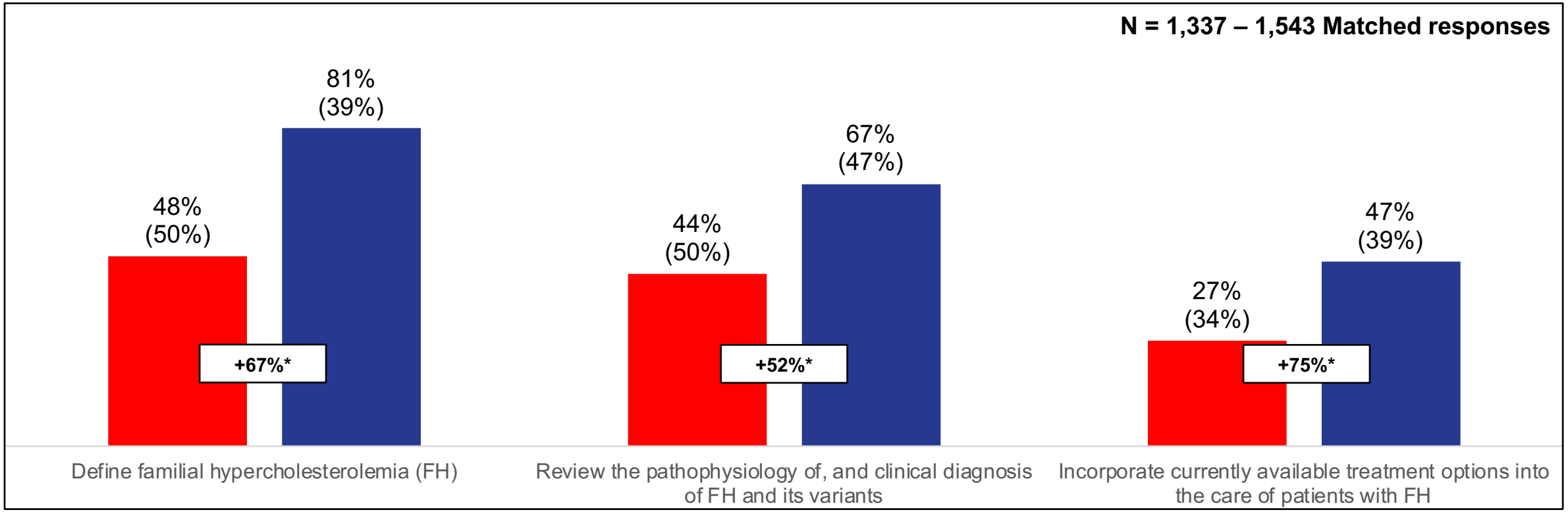
Learning Objective Analysis



- Across all three curriculum Learning Objectives, substantial and significant improvements were measured from low Pre-Test scores (< 49%)
- Strongest gains were measured on incorporating currently available treatment options into the care of patients with FH
  - Despite these improvements, Post-Test scores on this Objective were lowest (47%)
- Highest Post-Test scores were measured on the definition of familial hypercholesterolemia

* indicates significance, $p < 0.05$

Matched data, * indicates significance, $p < 0.05$

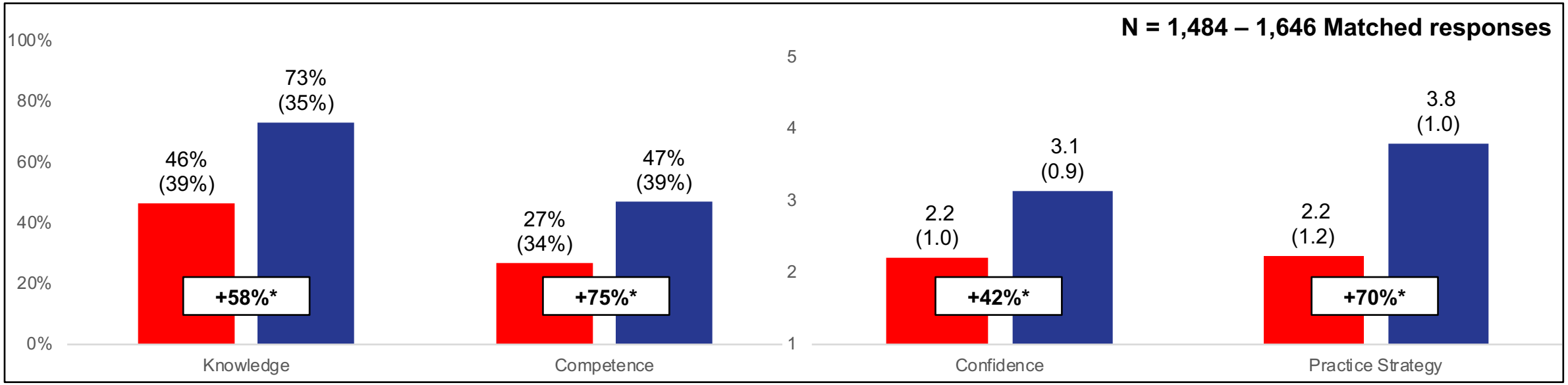
Learning Objective Analysis

Cohort comparison by profession

Learning Objective	Advanced Practice Nurses				Physicians			
	N	Pre-Test	Post-Test	Change	*N*	Pre-Test	Post-Test	Change
Define familial hypercholesterolemia (FH)	486	45% (50%)	80% (40%)	+76%*	222	53% (50%)	86% (35%)	+63%*
Review the pathophysiology of, and clinical diagnosis of FH and its variants	489	39% (49%)	66% (47%)	+67%*	207	45% (50%)	70% (46%)	+55%*
Incorporate currently available treatment options into the care of patients with FH	547	26% (32%)	45% (40%)	+76%*	244	32% (36%)	53% (38%)	+64%*

- For both advanced practice nurses and physicians, gains were measured from Pre- to Post-Test on each of the three curriculum Learning Objectives
- Across all three Objectives, advanced practice nurses achieved stronger improvements compared to physicians
- Physicians had higher Pre- and Post-Test scores on all three Objectives compared to advanced practice nurses
- For both groups, low scores were measured at Pre- and Post-Test on incorporating currently available treatment options into the care of patients with FH

Learning Domain Analysis



- In each of the four curriculum learning domains, substantial and significant gains were achieved from Pre- to Post-Test
- While strongest improvements were measured in Competence, this domain also had lowest Pre- and Post-Test scores; low scores were seen on both an item addressing initiation of therapy and another on when to refer for lipoprotein apheresis
- Higher scores in Knowledge were driven by an item about the definition of familial hypercholesterolemia
- In practice strategy, strong improvements to moderate Post-Test average ratings were given on intent to consider genetic testing for FH among patients with LDL-C > 190 mg/dL
- Low to moderate Pre- and Post-Test Confidence may reflect learner awareness of outstanding gaps in proficiency in this area

* indicates significance, $p < 0.05$

Learning Domain Analysis

Cohort comparison by profession

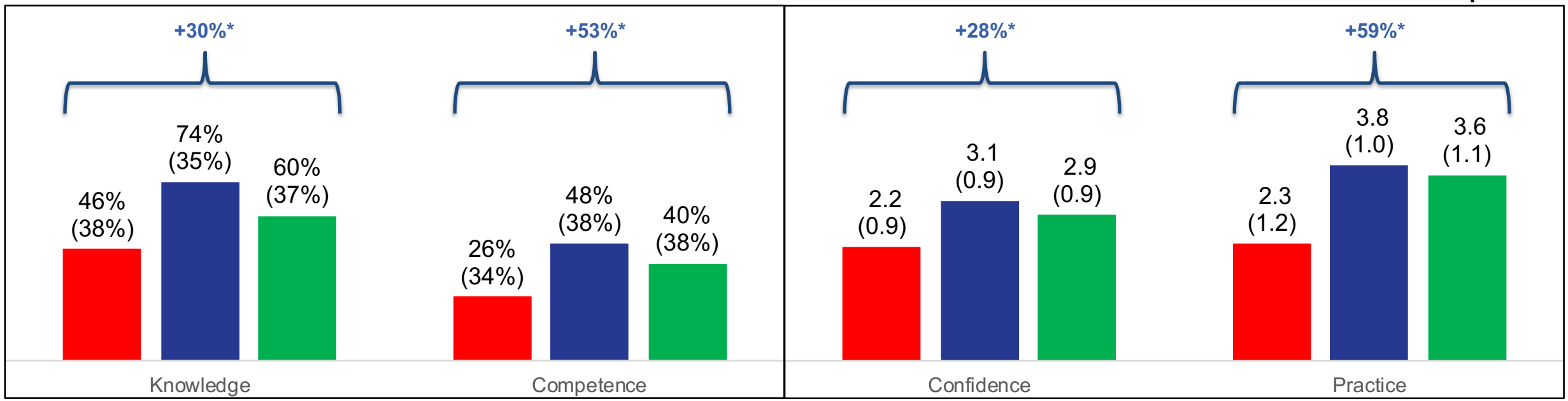
Matched data, * indicates significance, $p < 0.05$

Learning Domain	Advanced practice nurses				Physicians			
	N	Pre-Test	Post-Test	% Change	*N*	Pre-Test	Post-Test	% Change
Knowledge	532	42% (38%)	72% (37%)	+72%*	238	49% (39%)	79% (32%)	+59%*
Competence	547	26% (32%)	45% (40%)	+76%*	244	32% (36%)	53% (38%)	+64%*
Confidence	535	2.1 (0.9)	3.0 (0.9)	+41%*	222	2.4 (0.9)	3.3 (0.9)	+40%*
Practice	578	2.1 (1.1)	3.8 (1.0)	+79%*	240	2.4 (1.2)	3.7 (1.0)	+54%*

- When comparing the scores of advanced practice nurses and physicians by learning domain, both groups achieved substantial and significant gains from Pre- to Post-Test, across all four domains
- In all four learning domains, advanced practice nurses achieved stronger gains compared to physicians from Pre- to Post-Test
- Though they had stronger gains from Pre- to Post-Test, advanced practice nurses had lower Pre- and Post-Test scores compared to physicians in Knowledge, Competence, and Confidence, with similar ratings given in practice strategy

4-Week Retention Analysis

By Learning Domain



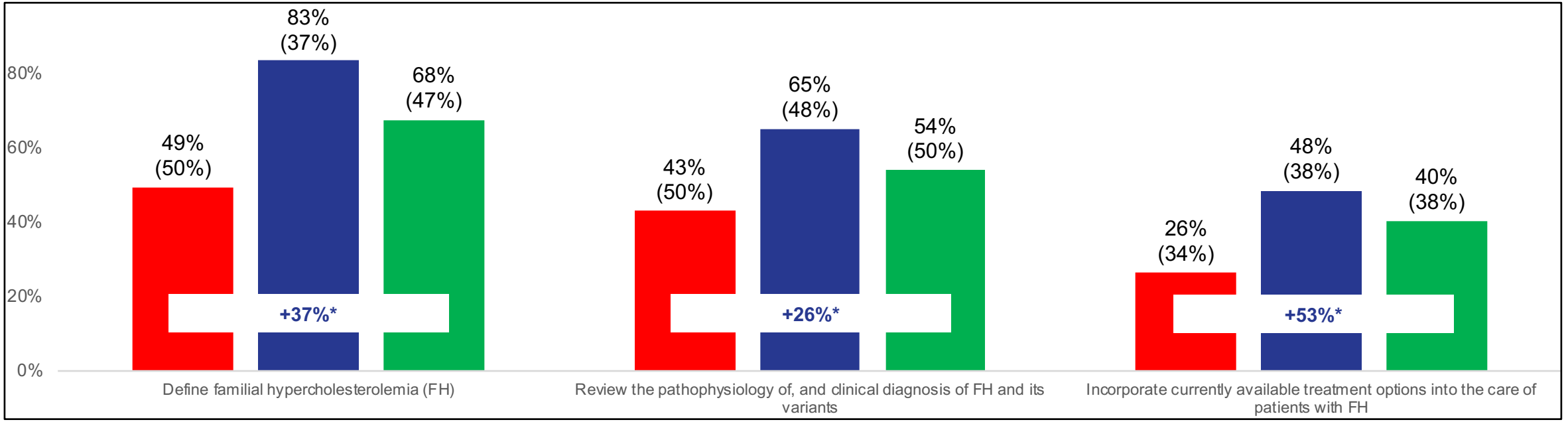
- Four to six weeks following their engagement in one of the curriculum sessions, learners were prompted to complete a brief Post Curriculum Assessment (PCA), which repeated items from each of the four curriculum learning domains
- In each of the four domains, substantial and significant net gains were achieved from Pre-Test to PCA measurements
  - Despite these gains, some score slippage was seen from Post-Test to PCA in all domains

* indicates significance, $p < 0.05$

4-Week Retention Analysis

By Learning Objective

N = 626 – 741 Matched responses



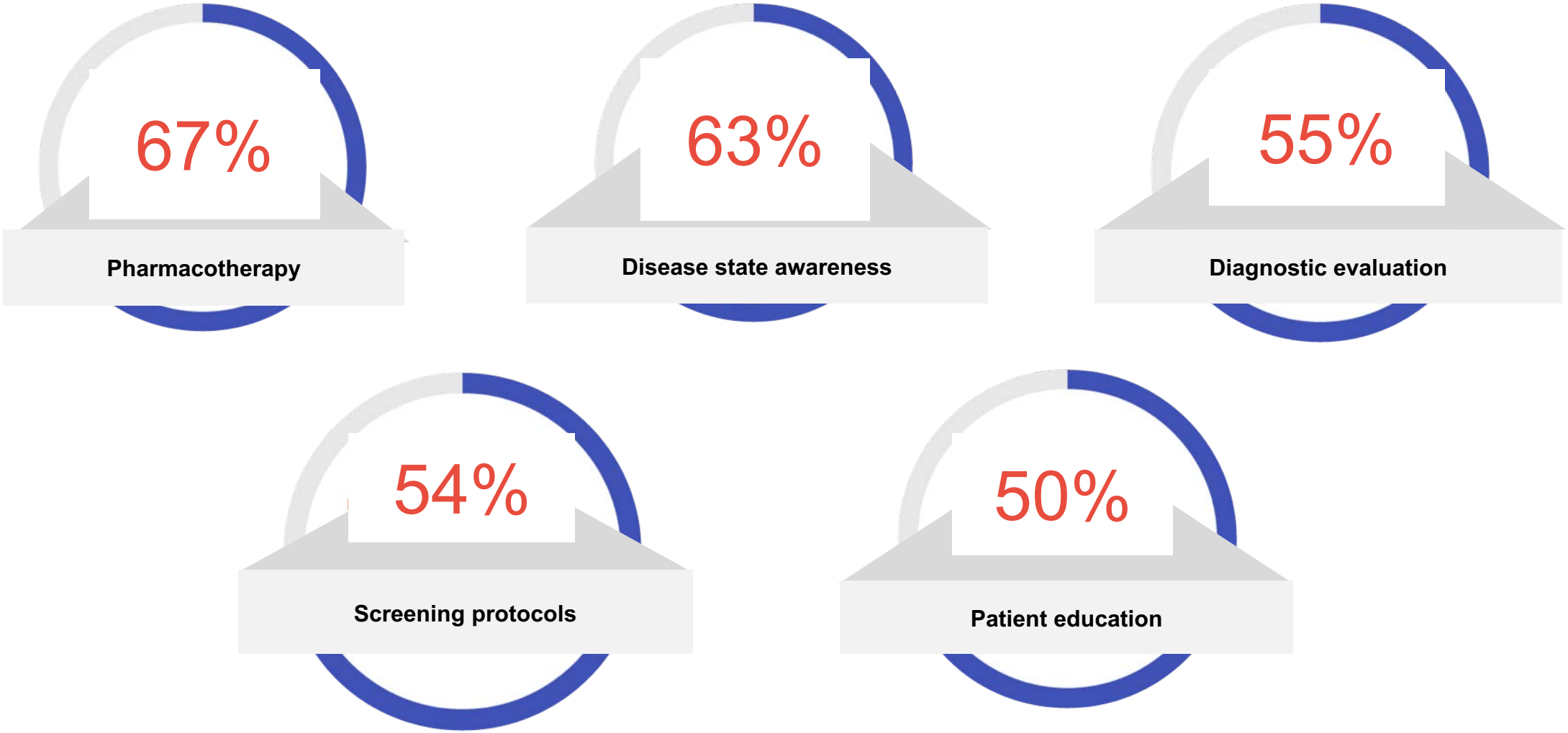
- When examining results by Learning Objective, substantial and significant net gains were achieved from Pre-Test to PCA measurements on each of the three Objectives, with some score slippage from Post-Test to follow-up
- The strongest gains, from the lowest Pre-Test scores, were measured in incorporating currently available treatment options into the care of patients with FH
- Across all Objectives, slippage in score from Post-Test to PCA measurements was seen

* indicates significance, $p < 0.05$

(4-week Post Assessment)

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

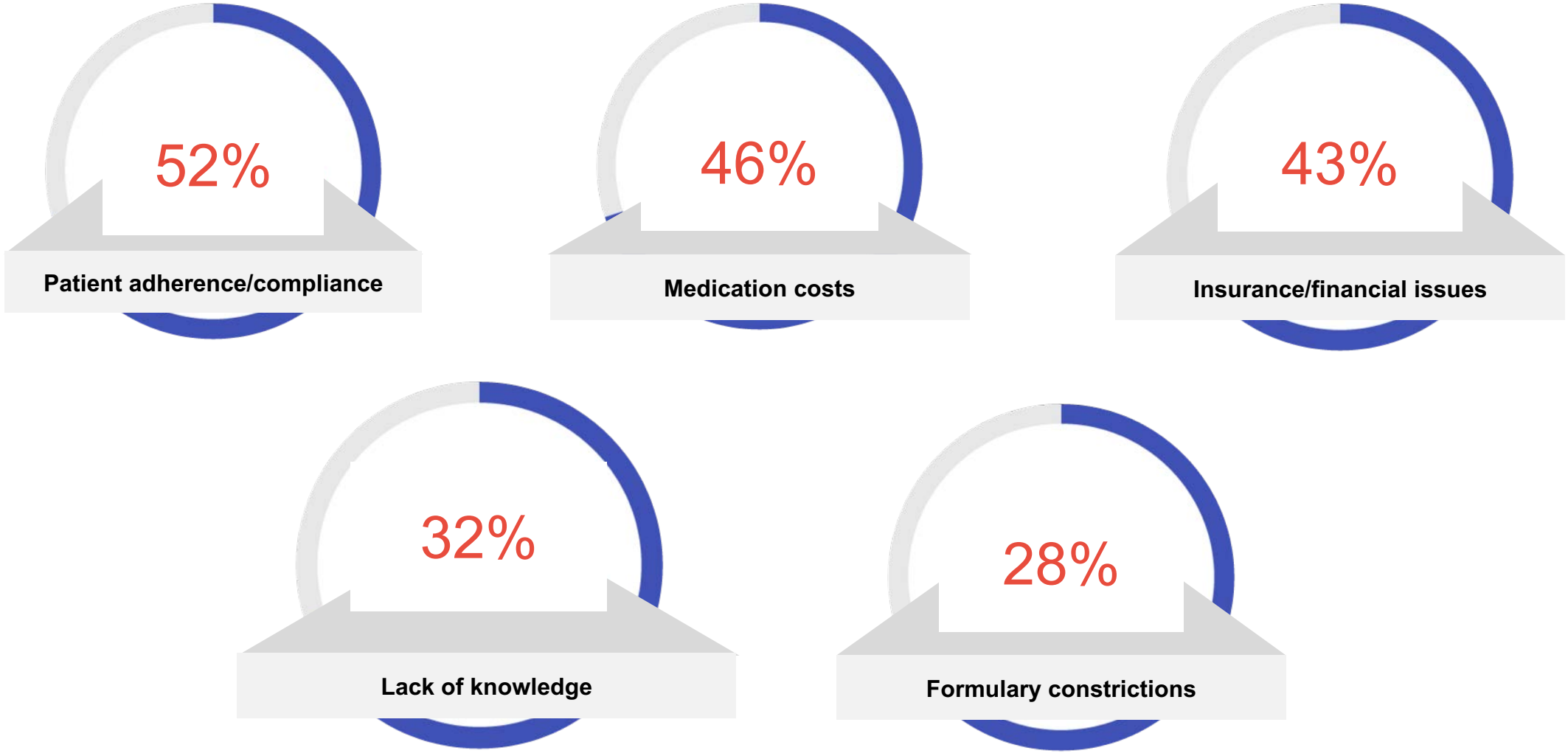
N = 1,427



(4-week Post Assessment)

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

N = 1,427



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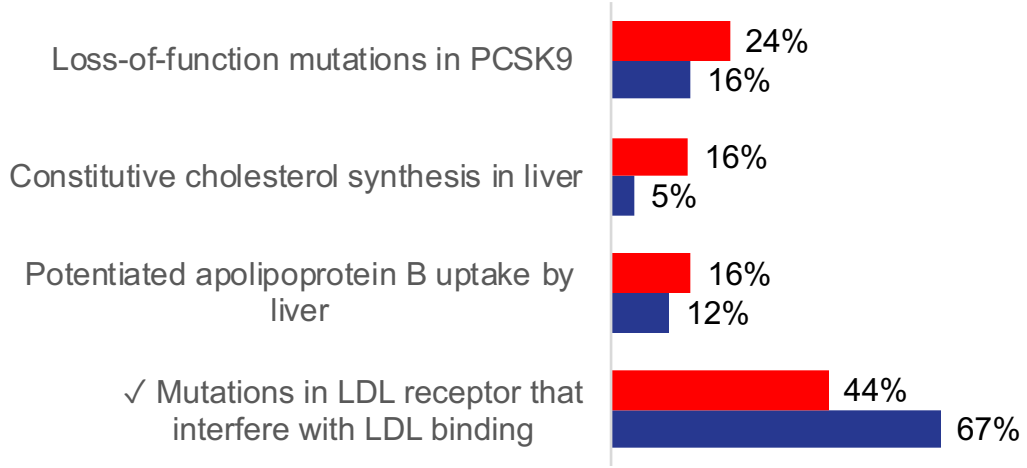
Identified Learning Gap:
Pathophysiology of FH

Despite improvements in score on a Knowledge item testing learners on the role of LDL receptor mutations in the pathophysiology of FH, low Post-Test scores were measured

Which of the following is a pathophysiologic mechanism underlying forms of FH?

Results:

- At Post-Test, 67% of learners correctly answered: “Mutations in LDL receptor that interfere with LDL binding”



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Identified Learning Gap:
Selecting a high-intensity statin as first-line therapy for FH

On a Competence item, learners were presented with the case of a patient with a family history including a death from MI and the monogenic LDL-R mutation associated with FH. When asked to select initial therapy for her, learners struggled to correctly identify the need to start a high-intensity statin.

28 y/o woman presents with xanthoma on Achilles tendons. Workup identifies LDL-C 435 mg/dL, total cholesterol 495 mg/dL; other findings WNL. Family Hx: Father died of MI at age 49 years. Genetic testing identifies monogenic LDL-R mutation associated with FH. No current medications. Which of the following might be appropriate at this time?

Results:

- At Post-Test, 52% of learners correctly answered: “Initiate high-intensity statin therapy”

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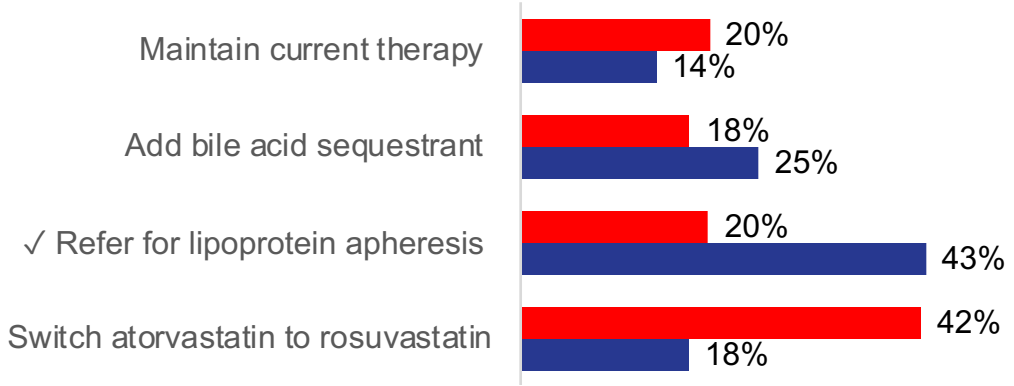
Identified Learning Gap:
When to refer FH patients for lipoprotein apheresis

On another Competence question describing the case of a patient with elevated LDL-C despite adherence to lipid-lowering therapies and lifestyle modifications, learners struggled at Post-Test to correctly identify the need to refer for lipoprotein apheresis

39 y/o man with history of unstable angina and heterozygous FH. Today's workup: LDL-C 138 mg/dL; other findings WNL. Lipid-lowering therapy: Atorvastatin 80 mg qd, ezetimibe 10 mg qd, evolocumab 420 mg q1month. Reports adherence to medical therapy, exercise, and heart-healthy diet. Which of the following might be appropriate at this time?

Results:

- At Post-Test, 43% of learners correctly answered: "Refer for lipoprotein apheresis"



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Overall Educational Impact

- Substantial, significant improvements were seen across all four curriculum learning domains, from Pre- to Post-Test (Knowledge, Competence, Confidence, and practice strategy)
    - These gains were stronger for advanced practice nurses compared to physicians across all domains, though physicians achieved higher scores in Knowledge and Confidence
    - These gains were seen across all individual Knowledge and Competence items, with improvements ranging from 52% to 115%
- Significant improvements ranging from 52% to 75% were measured across all Learning Objectives, with all Post-Test scores between 47% and 81%
- Though practice strategy ratings (to consider genetic testing for FH among patients with LDL-C > 190 mg/dL) increased to a Post-Test average of 3.8, lower Post-Test Confidence ratings (3.1) suggest learner awareness of gaps in Knowledge and Competence
- The analysis of the Knowledge and Competence domains identified three **opportunities for further education in the management of patients with FH**
    - Despite improvements in score on a Knowledge item testing learners on the role of LDL receptor mutations in the **pathophysiology of FH**, low Post-Test scores were measured
    - On a Competence item, learners were presented with the case of a patient with a family history including a death from MI and the monogenic LDL-R mutation associated with FH; learners struggled with **selecting a high-intensity statin as first-line therapy for FH**
    - On another Competence question describing the case of a patient with elevated LDL-C despite adherence to lipid-lowering therapies and lifestyle modifications, learners struggled at Post-Test with **when to refer for lipoprotein apheresis**

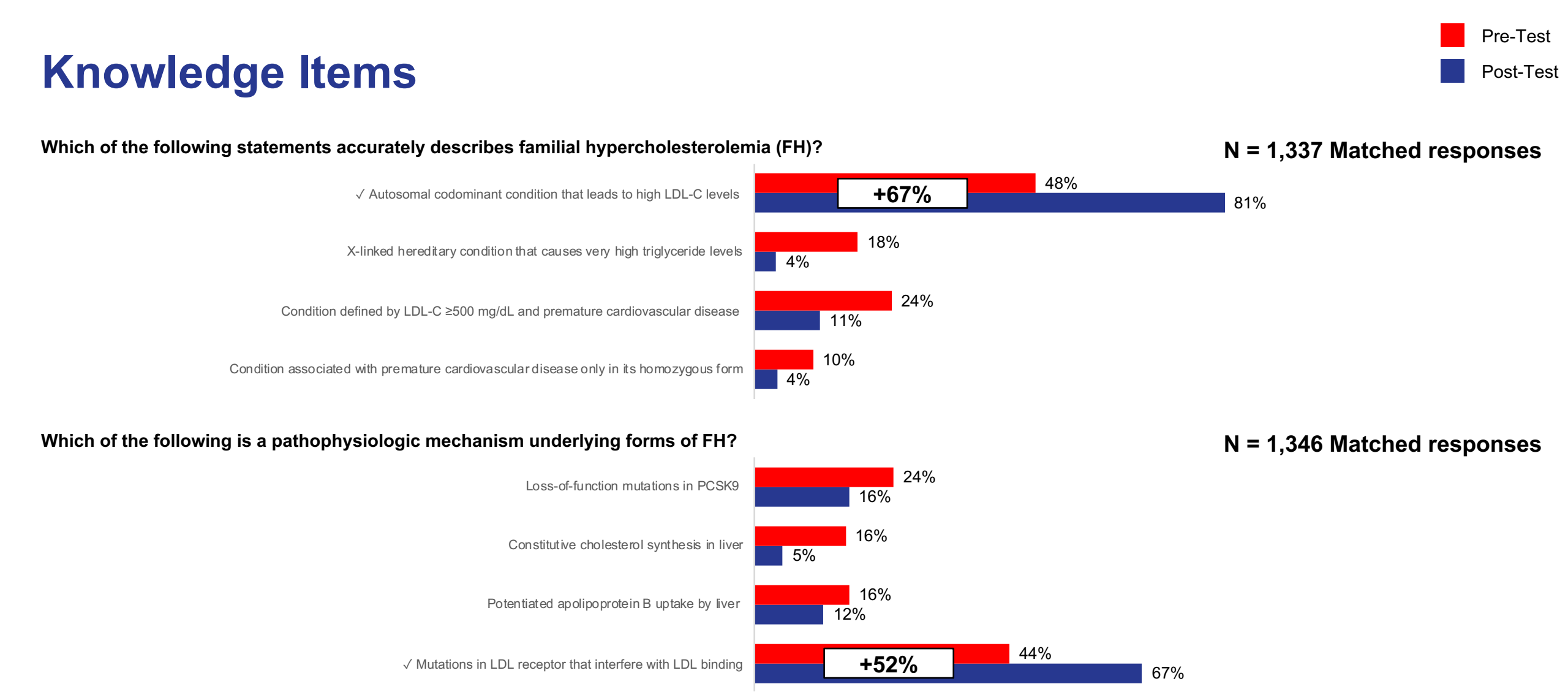
Appendix

Slides 27 – 29: Pre-Test to Post-Test matched item responses

Slides 30 – 32: Pre-Test, Post-Test, and PCA matched item responses*

*Both sets of response distributions are included due to the smaller sample size of matched PCA respondents

Knowledge Items



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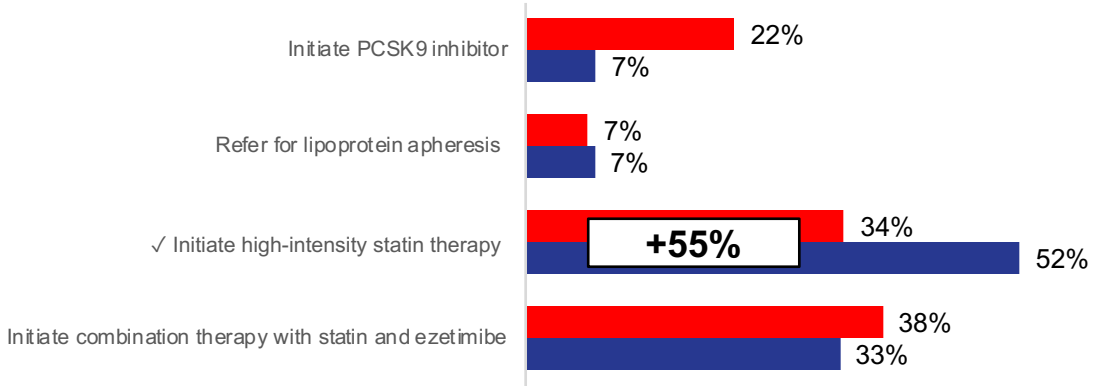
Competence Items

Pre-Test
Post-Test

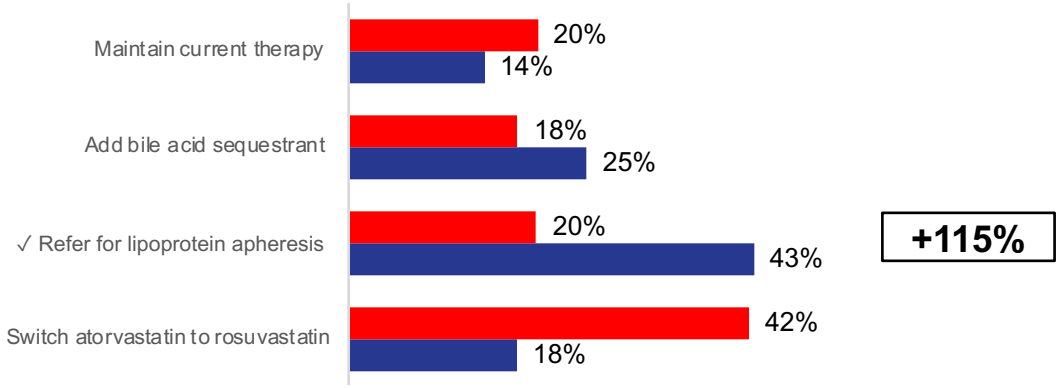
28 y/o woman presents with xanthoma on Achilles tendons. Workup identifies LDL-C 435 mg/dL, total cholesterol 495 mg/dL; other findings WNL. Family Hx: Father died of MI at age 49 years. Genetic testing identifies monogenic LDL-R mutation associated with FH No current medications. Which of the following might be appropriate at this time?

N = 1,431 Matched responses



39 y/o man with history of unstable angina and heterozygous FH. Today's workup: LDL-C 138 mg/dL; other findings WNL. Lipid-lowering therapy: Atorvastatin 80 mg qd, ezetimibe 10 mg qd, evolocumab 420 mg q1month. Reports adherence to medical therapy, exercise, and heart-healthy diet. Which of the following might be appropriate at this time?

N = 1,419 Matched responses



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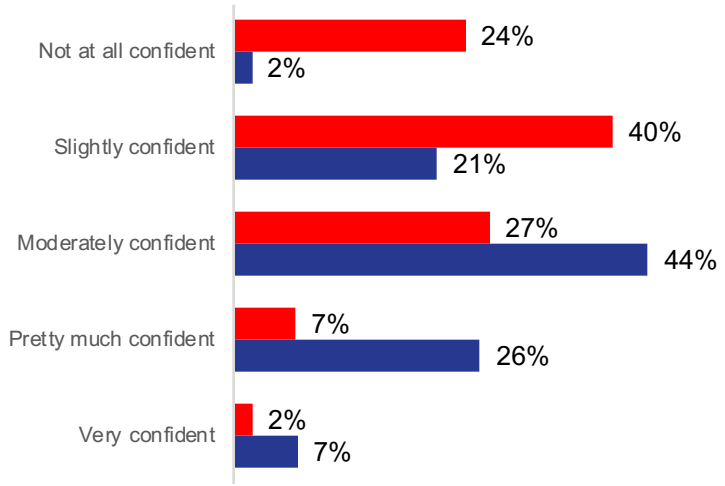
Confidence and Practice Strategy Items

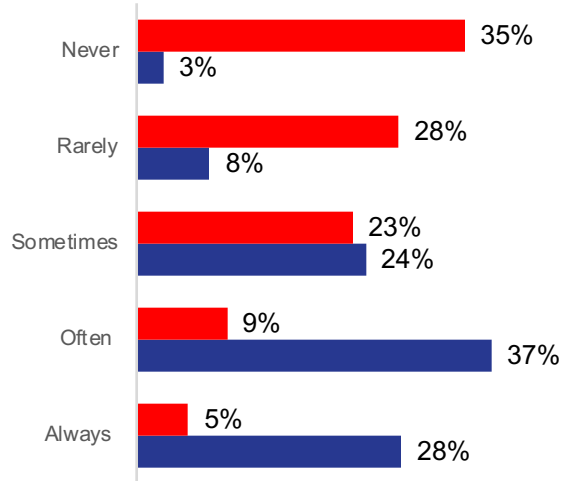
How confident are you in your ability to manage patients with FH?

N = 1,484 Matched responses



How often do you consider genetic testing for FH among patients with LDL-C >190 mg/dL?

N = 1,646 Matched responses



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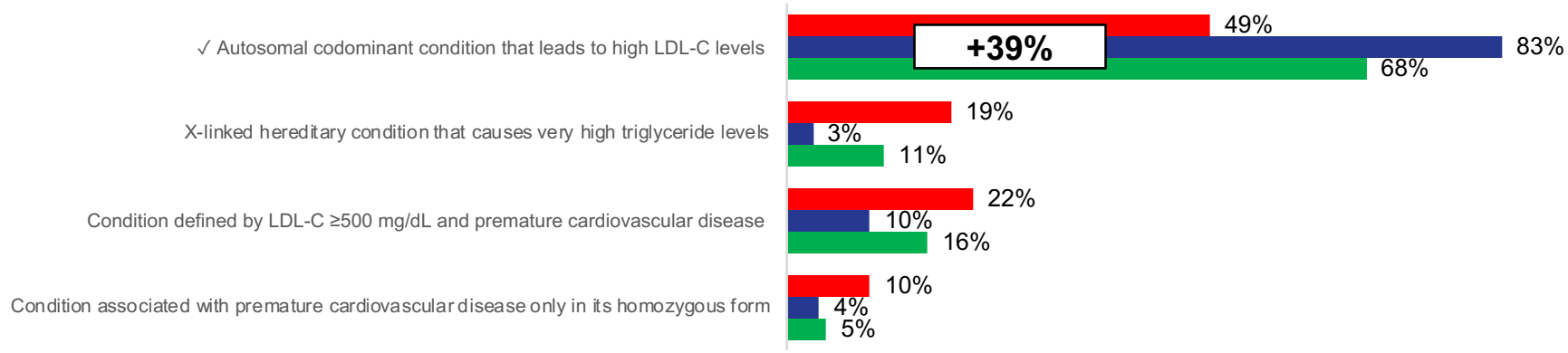
Knowledge Items

Post Curriculum Assessment (PCA)

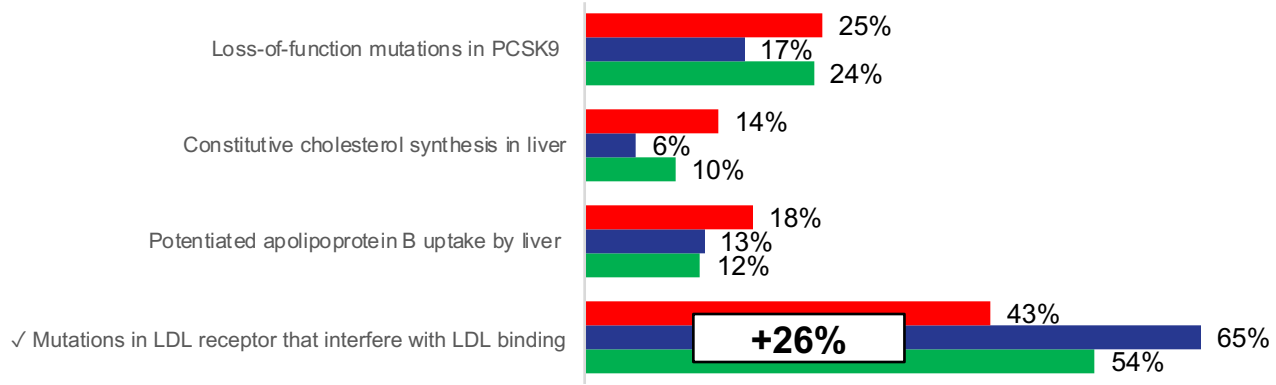
Which of the following statements accurately describes familial hypercholesterolemia (FH)?

N = 626 Matched responses



Which of the following is a pathophysiologic mechanism underlying forms of FH?

N = 636 Matched responses



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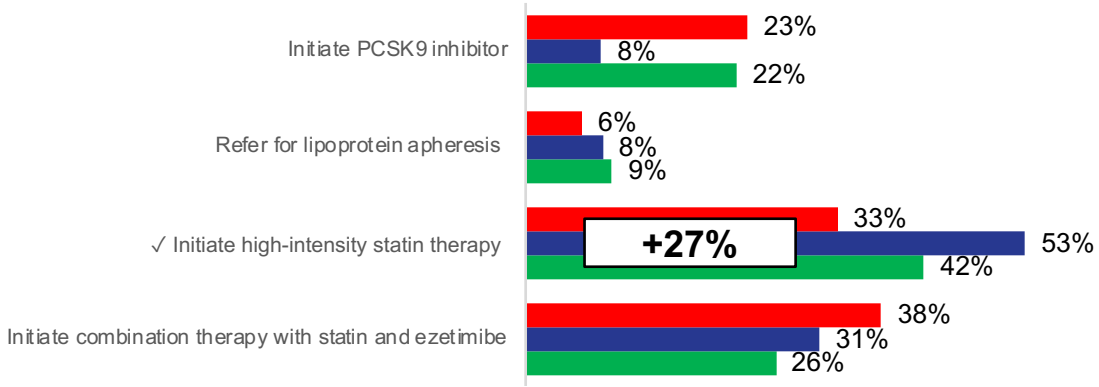
Competence Items

Post Curriculum Assessment (PCA)

Pre-Test
Post-Test
PCA

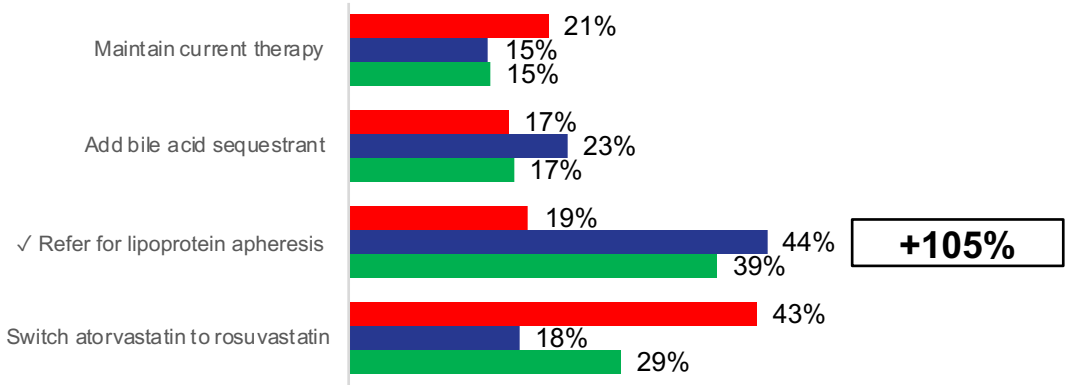
28 y/o woman presents with xanthoma on Achilles tendons. Workup identifies LDL-C 435 mg/dL, total cholesterol 495 mg/dL; other findings WNL. Family Hx: Father died of MI at age 49 years. Genetic testing identifies monogenic LDL-R mutation associated with FH No current medications. Which of the following might be appropriate at this time?

N = 686 Matched responses



39 y/o man with history of unstable angina and heterozygous FH. Today's workup: LDL-C 138 mg/dL; other findings WNL. Lipid-lowering therapy: Atorvastatin 80 mg qd, ezetimibe 10 mg qd, evolocumab 420 mg q1month. Reports adherence to medical therapy, exercise, and heart-healthy diet. Which of the following might be appropriate at this time?

N = 689 Matched responses



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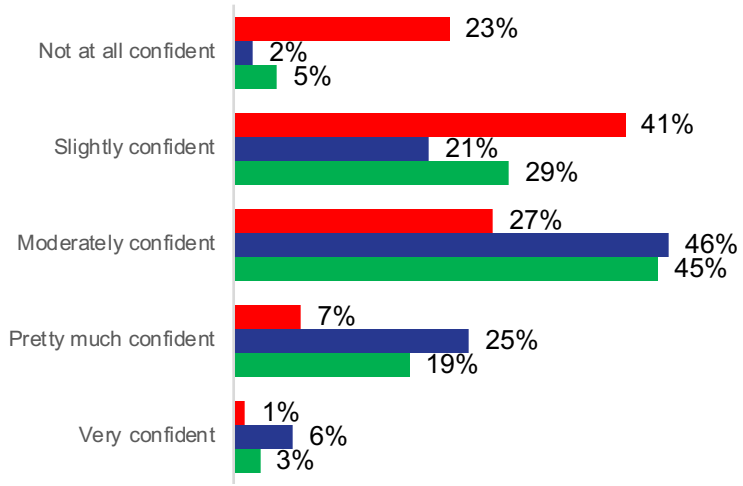
Confidence and Practice Strategy Items

Post Curriculum Assessment (PCA)

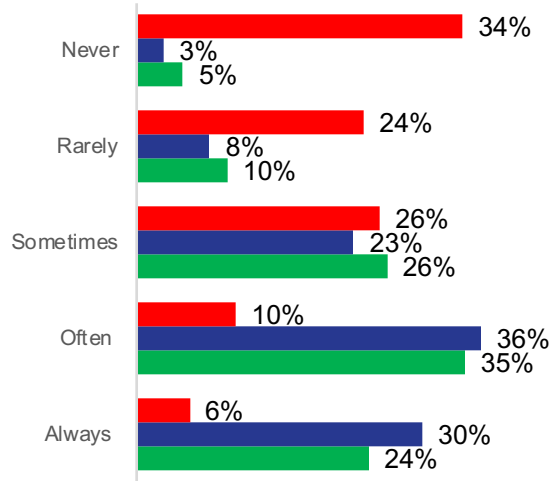
How confident are you in your ability to manage patients with FH?

N = 711 Matched responses



How often do you consider genetic testing for FH among patients with LDL-C >190 mg/dL?

N = 776 Matched responses



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