NACE *Conversations* in Primary Care 2019

Final Live Outcomes Report

The Epidemic of NASH: Current and Emerging Management and Treatment Strategies

Intercept Pharmaceuticals, INC. • MED-HEP-668

September 26, 2019

RealCME

NACE

NACE *Conversations* in Primary Care 2019

The Epidemic of NASH: Current and Emerging Management and Treatment Strategies

723 Participants

1 Activity

530 certificates issued to date

This education has the potential to impact 1,694,828 patients on an annual basis.

29,334–35,852 Patients Weekly

2019 Conversations Activity	Date	Participants
Conversations In Primary Care 2019 Episode 3	3/30/19	723
Live Guarantee: 500	**Total**	**723**

Enduring CME Webcast

Speaker

Kalyan Ram Bhamidimarri, MD, MPH
Associate Professor
Chief, Division of Hepatology
University of Miami
Miami, FL

COURSE SUMMARY

Cost: Free

Start Date: 05/15/2019

Expiration Date: 05/14/2020

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

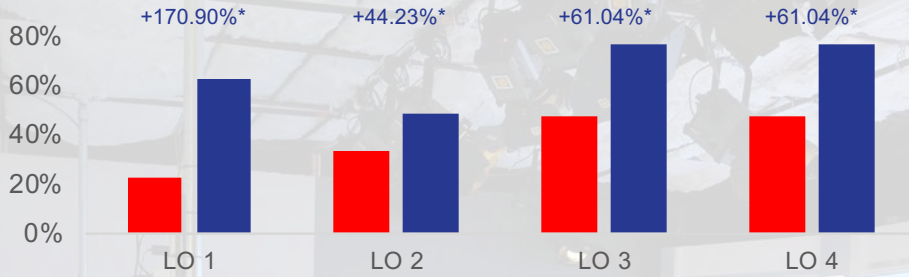
Format: Webcast

Estimated Time To Complete CME Activity: 1.0 hour

Credits: 1.0 *AMA PRA Category 1 Credit(s)™*; 1.0 AANP Contact hour which includes 0.25 pharmacology hours

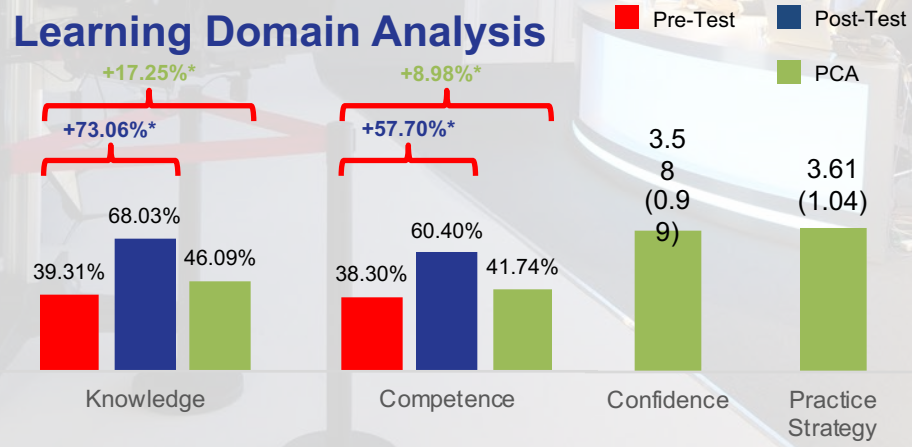
Hardware/Software Requirements: Any web browser

Learning Gains Across Objectives



- **LO 1:** Identify patients at high risk for nonalcoholic fatty liver disease (NAFLD)
- **LO 2:** Distinguish non - alcoholic fatty liver (NAFL) from nonalcoholic steatohepatitis (NASH) and understand how to stage the disease
- **LO 3:** Implement ongoing evidence - based general management of patients with NASH
- **LO 4:** Describe the available and emerging treatment options for patients with NASH

Learning Domain Analysis

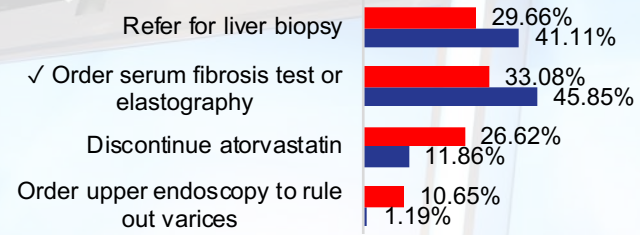


- Learners demonstrated strong changes from Pre- to Post-Test in ability to distinguish NASH from NAFLD, recognize patients at risk for NASH, recommend appropriate diagnostic evaluations and general medical care. Significant improvements persisted 4 weeks after the program though with some slippage from Post-Test.
- After 4 weeks, learners reported greater understanding of how to perform non-invasive testing for NAFLD, increased identification and screening of patients at-risk for NAFLD, and recommending lifestyle modifications more often to patients diagnosed with NASH, though there are opportunities for further education in this area.

Persistent Learning Gaps/Needs

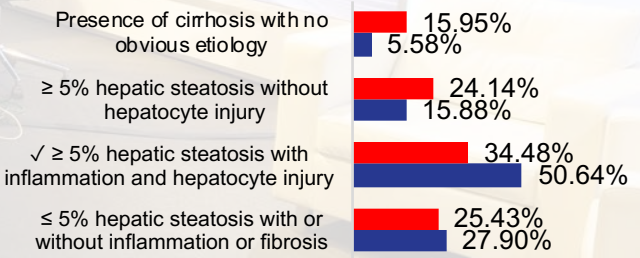
Role of non-invasive testing in diagnosis of liver disease

On a competence item presenting the case of a patient with obesity, type 2 diabetes, ASCVD, hypertension, dyslipidemia, and possible NASH, learners struggled at Post-Test to identify the need to order serum fibrosis test or elastography.



Distinguishing between NASH and other forms of NAFLD

On a Knowledge item criteria distinguishing NASH from other forms of NAFLD, learners struggled to identify the correct response at Post-Test.



LEARNING RETENTION: Although net gains were measured from Pre-test to PCA, score slippage and persistent educational gaps indicate a continued need for education on the recognition and management of NASH.

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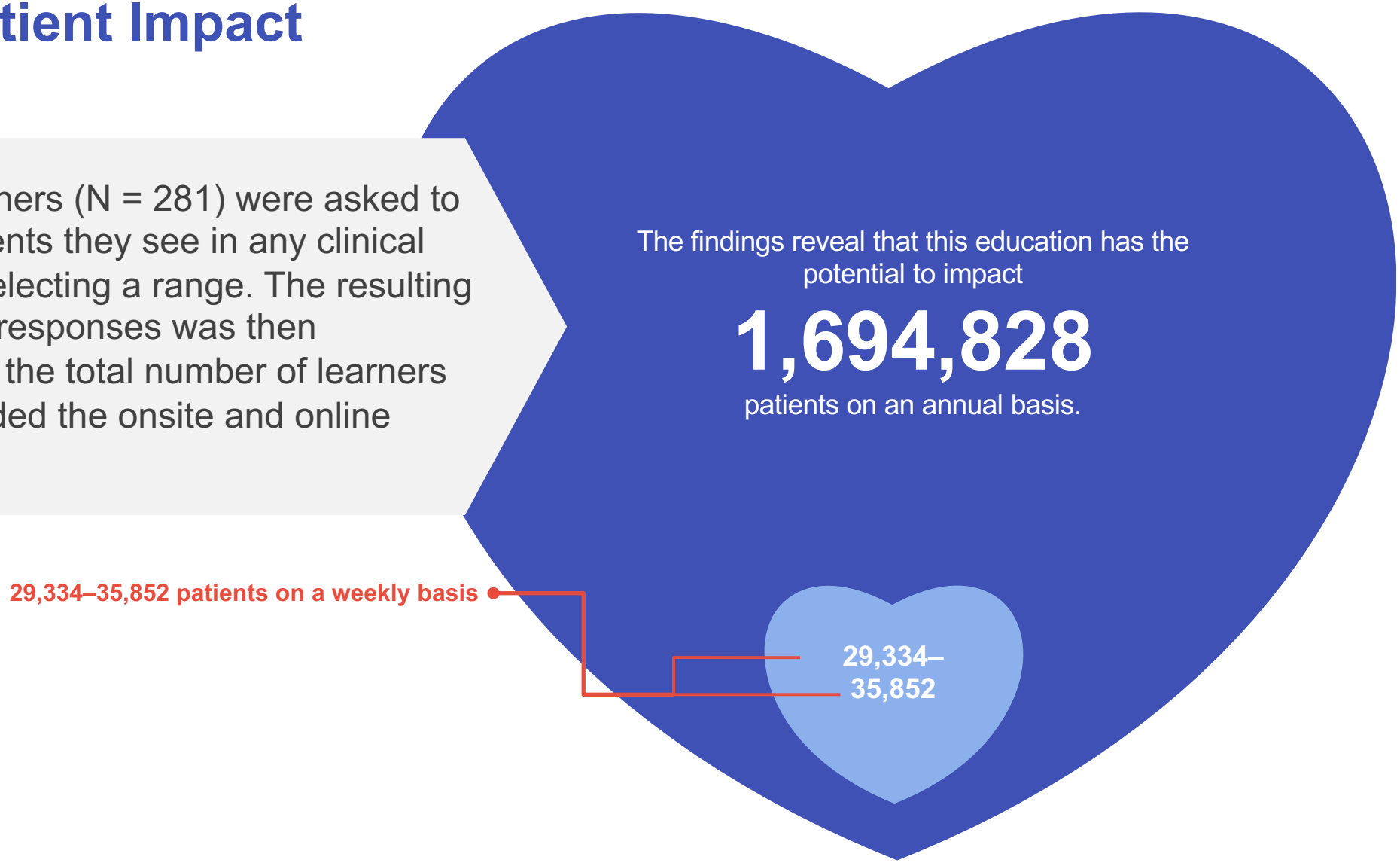
Curriculum Patient Impact

In the evaluation, learners (N = 281) were asked to report how many patients 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 (723) who have attended the onsite and online meetings.



Course Director

Kalyan Ram Bhamidimarri, MD, MPH
Associate Professor
Chief, Division of Hepatology
University of Miami
Miami, FL

Faculty

Kalyan Ram Bhamidimarri, MD, MPH
Associate Professor
Chief, Division of Hepatology
University of Miami
Miami, FL

Activity Planning Committee

Gregg Sherman, MD

Michelle Frisch, MPH, CHCP

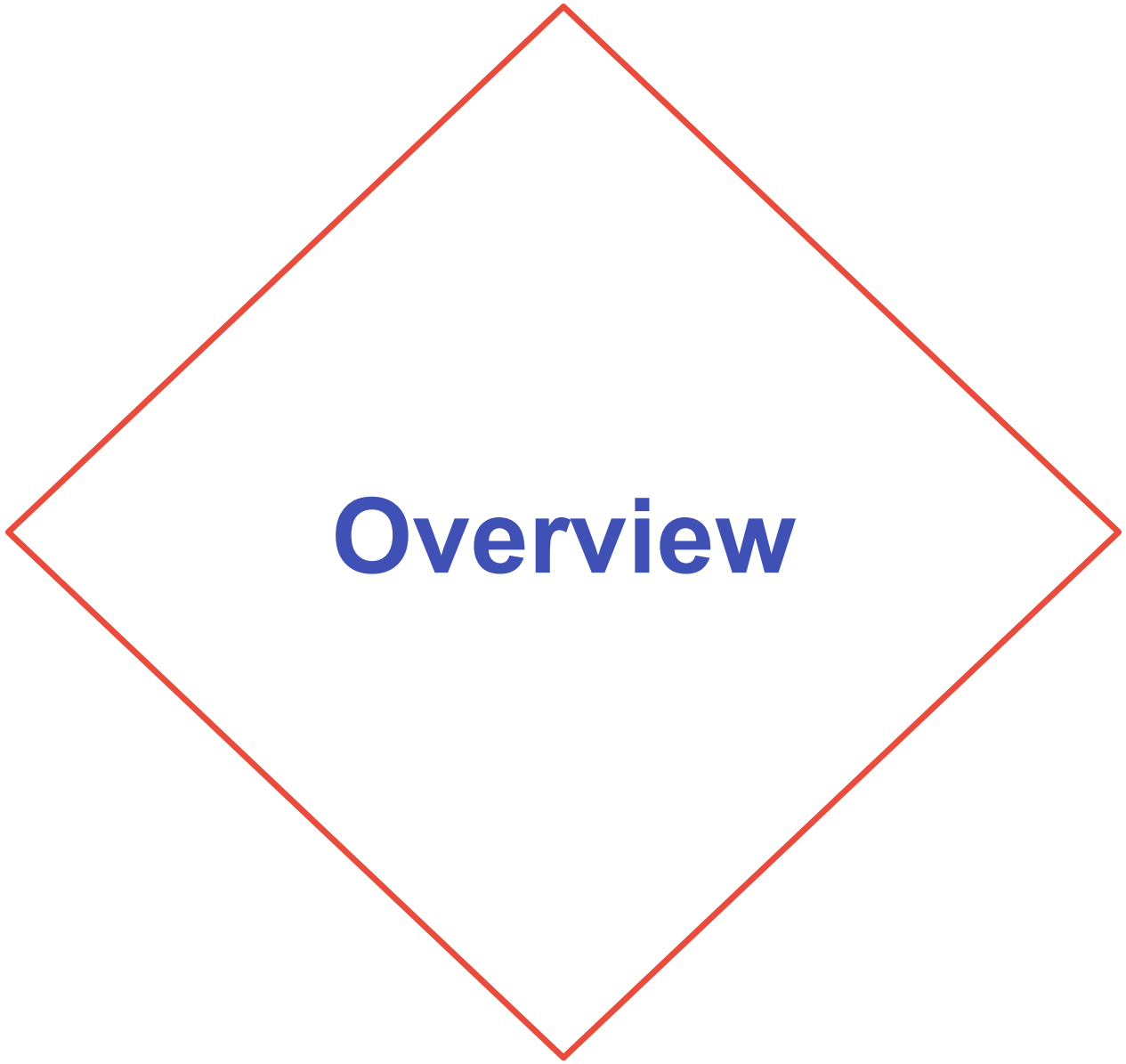
Sandy Bihlmeyer, M.Ed.

Sheila Lucas, CWEP

Deborah Paschal, CRNP

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

- Identify patients at high risk for nonalcoholic fatty liver disease (NAFLD)
- Distinguish non-alcoholic fatty liver (NAFL) from nonalcoholic steatohepatitis (NASH) and understand how to stage the disease
- Implement ongoing evidence-based general management of patients with NASH
- Describe the available and emerging treatment options for patients with NASH

NACE *Conversations* in Primary Care

Curriculum Overview

One Live Virtual CME Symposia

Enduring CME Symposium Webcast

https://www.naceonline.com/courses/the-epidemic-of-nash-current-and-emerging-management-and-treatment-strategies

Speaker

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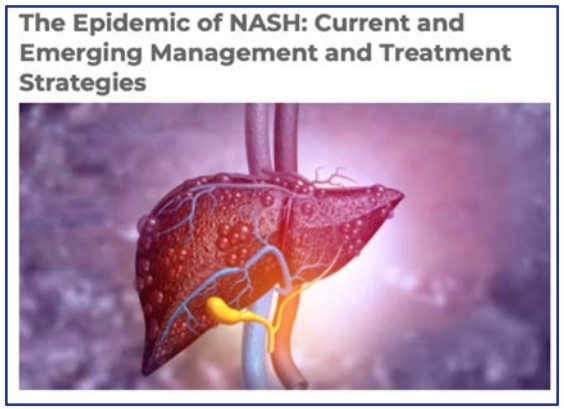

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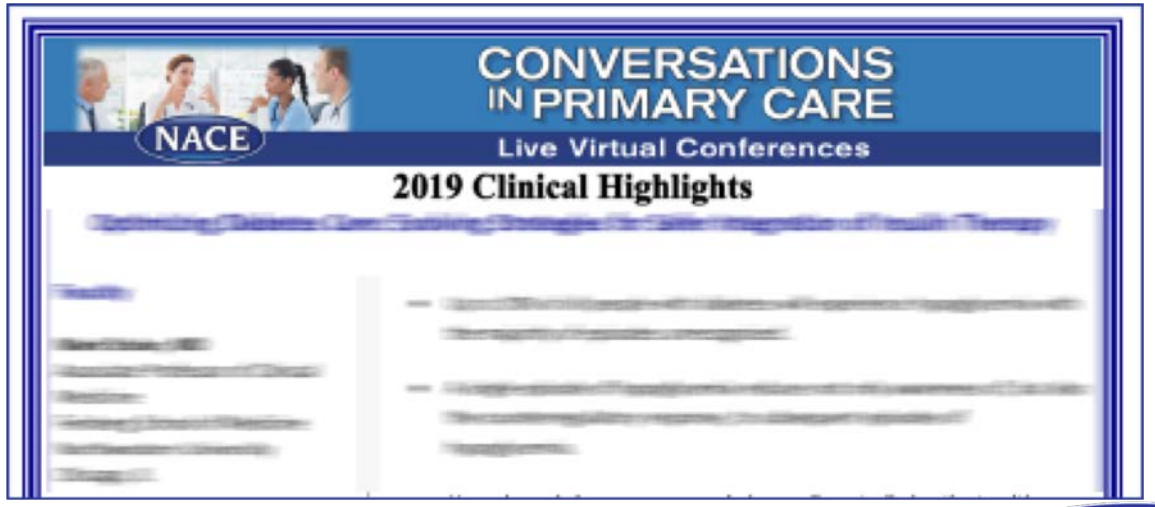
Hardware/Software Requirements: Any web browser

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

2019 Conversations Activity	Date	Participants
Conversations In Primary Care 2019 Episode 3	3/30/19	723
Live Guarantee:500	**Total**	**723**

Level 1
Participation
Demographics
Patient Reach

Participation

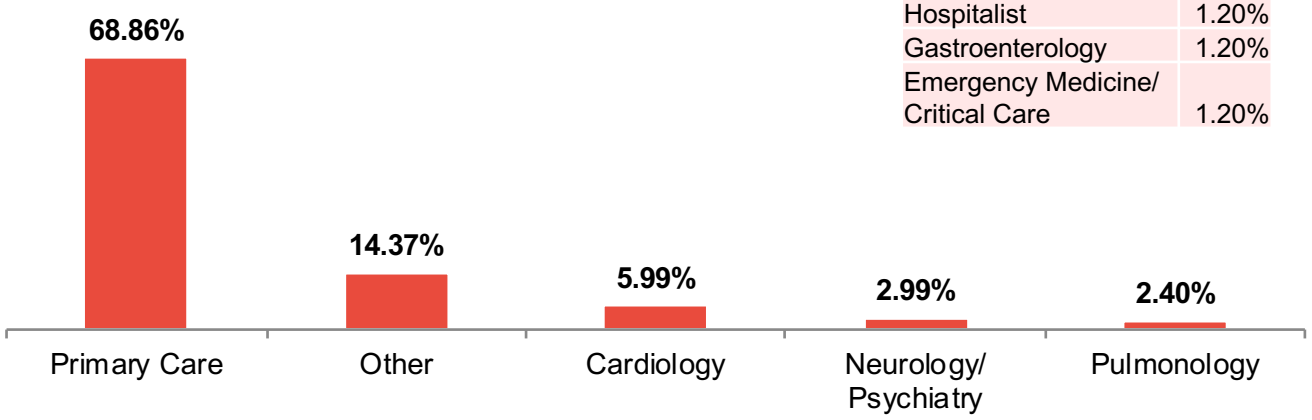
723
Total Attendees

1 Activity

N = 297

Level 1: Demographics and Patient Reach

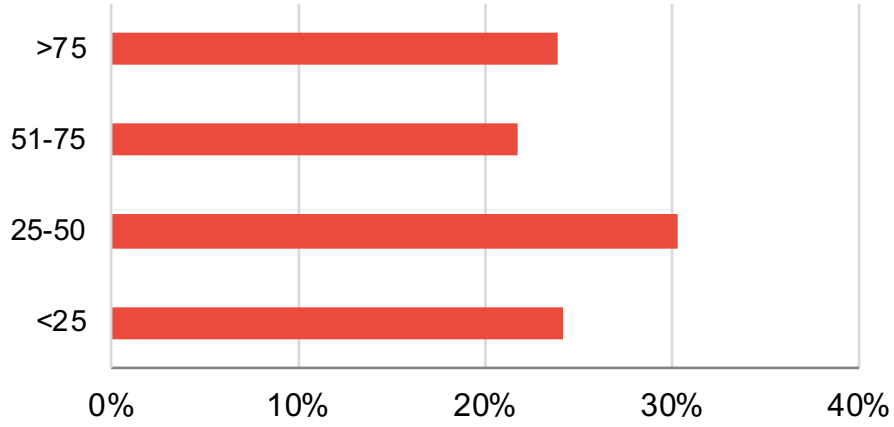
Specialty



Under 2%	
Endocrinology	1.80%
Hospitalist	1.20%
Gastroenterology	1.20%
Emergency Medicine/ Critical Care	1.20%

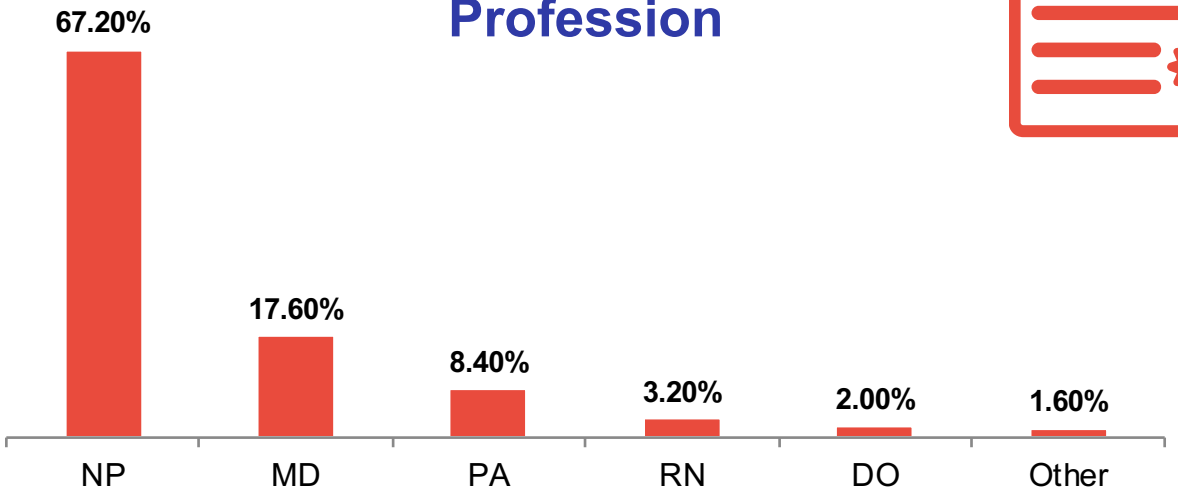
Patient Care Focus: 92%

Patients seen each week, in any clinical setting:

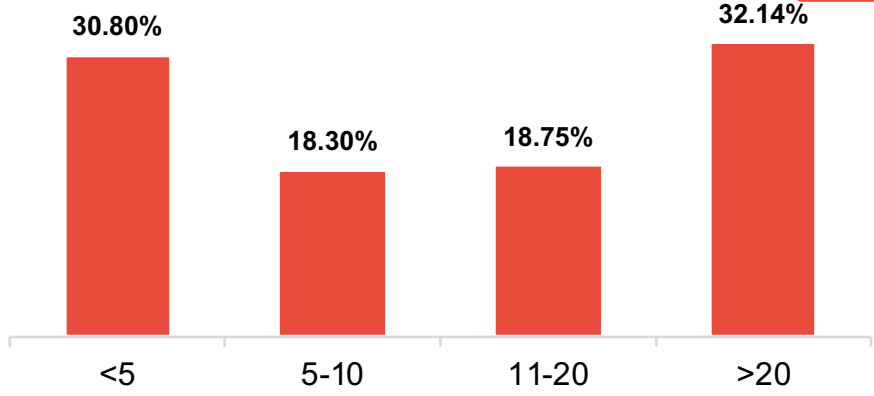


Average number of patients seen each week per clinician: 49

Profession



Years in Practice



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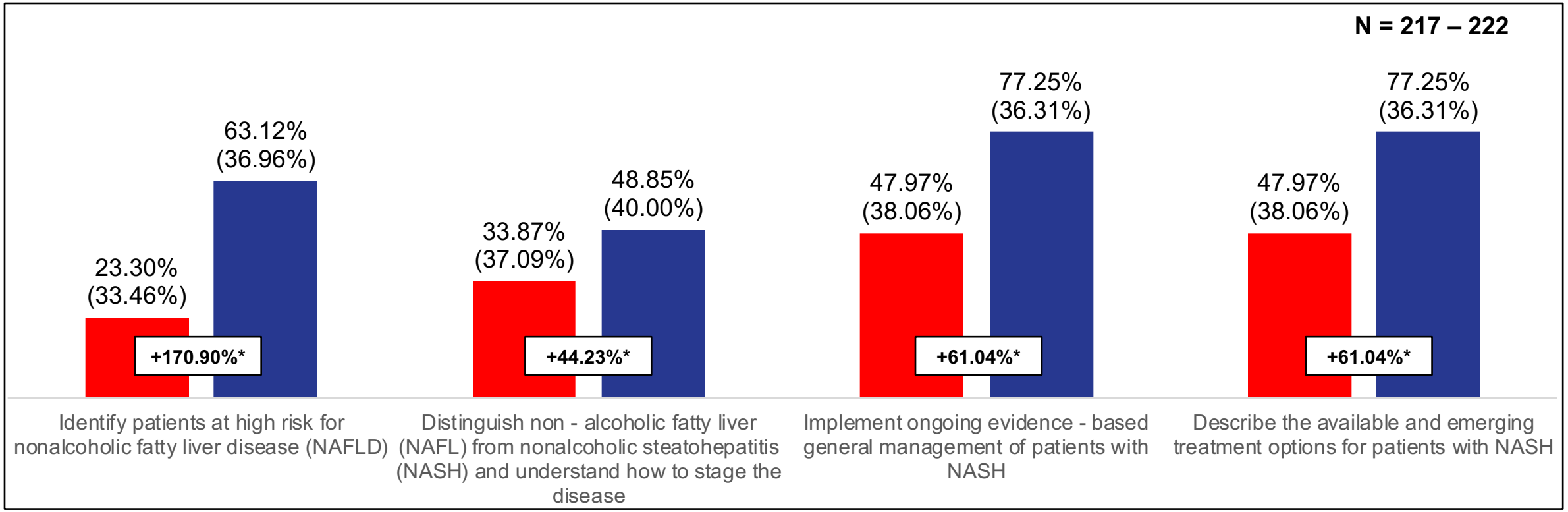
Level 2-5:
Outcomes Metrics

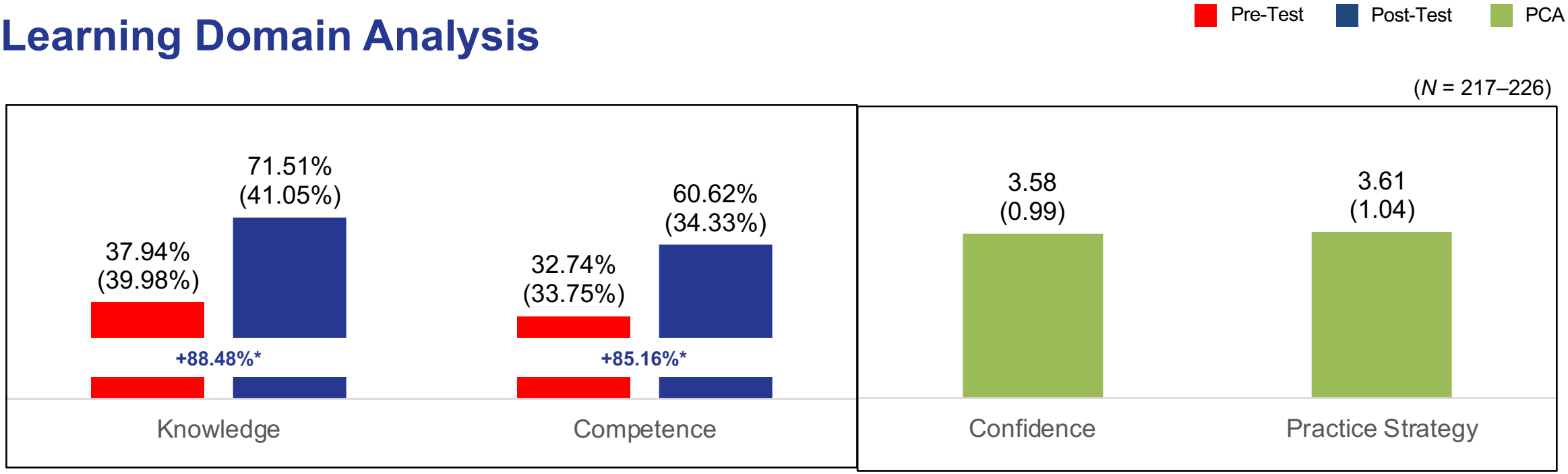
Learning Objective Analysis



- Substantial and significant improvements were achieved from Pre- to Post-Test on all four curriculum Learning Objectives, ranging from 61% to 171% improvements
- In spite of this, Post-Test scores remained low to moderate (49% to 77%), due to low Pre-Test scores (23% to 48%)
- Low scores in distinguishing NAFL from NASH were driven by a Knowledge item on distinguishing symptoms
- The highest scores at Post-Test (80%) and greatest improvements from Pre-Test (589%) were measured on an item on which racial/ethnic groups are at the lowest risk for developing NASH, mapped to the first Learning Objective above

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

Learning Domain Analysis

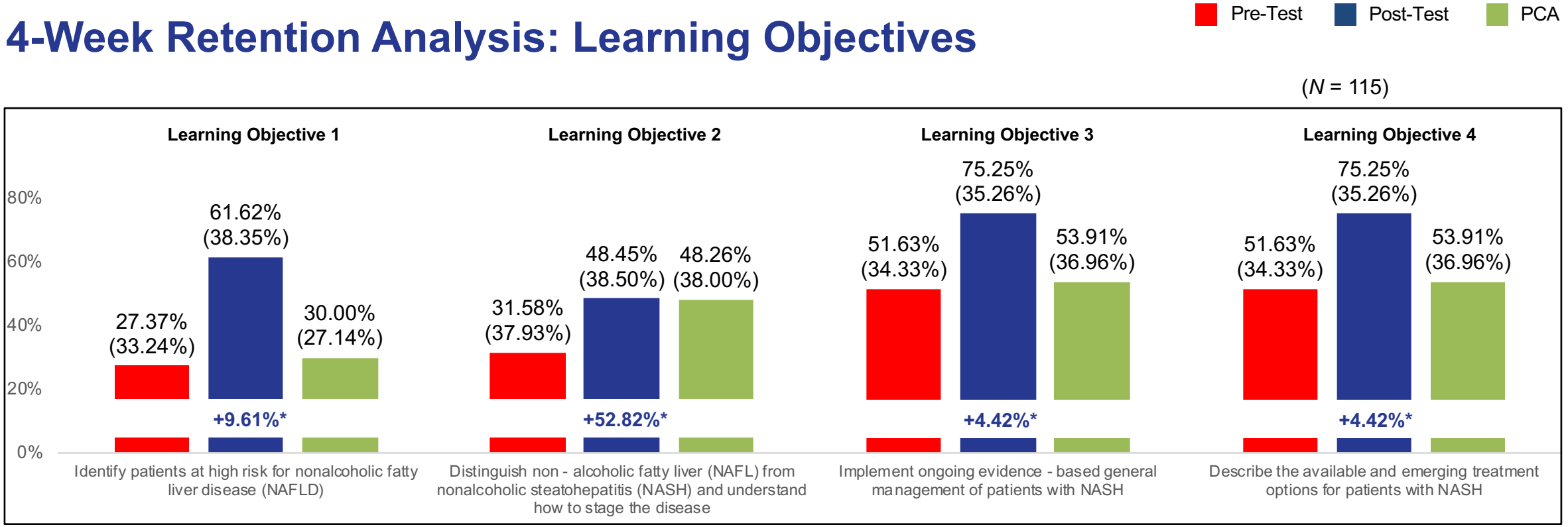


- Substantial and significant improvements were measured from Pre- to Post-Test in both Knowledge and Competence
- These gains were driven by a Knowledge item on the variation in risk for NAFLD by ethnic group (+589%), and by a Competence item assessing use of strategies for evidence-based general medical, and non-pharmacologic care, for patients with NASH (+105%)
- In Confidence and Practice Strategy, which were measured at 4 week follow-up only, moderate scores were observed. Learners reported greater understanding of how to perform non-invasive testing for NAFLD, increased identification and screening of patients at-risk for NAFLD, and recommending lifestyle modifications more often to patients diagnosed with NASH, though there are opportunities for further education in this area.

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

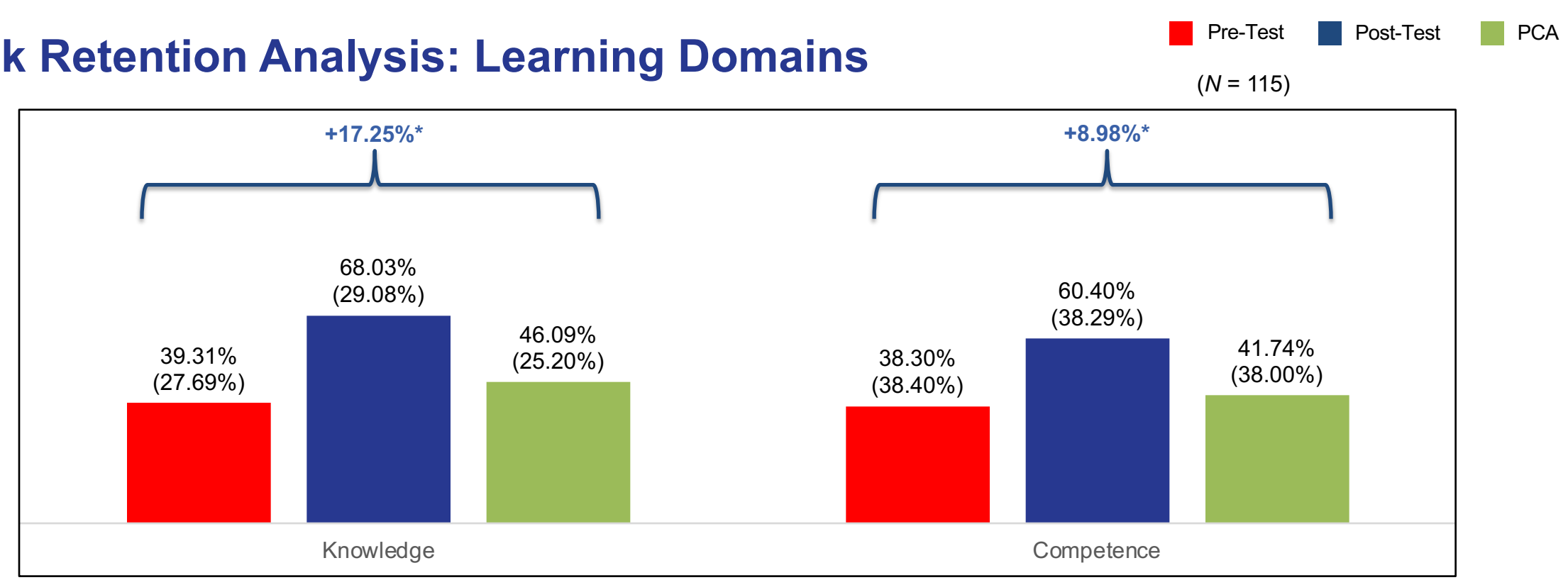


- In addition to collecting Confidence and Practice data for the curriculum, the Post Curriculum Assessment (PCA) repeated questions from the Knowledge and Competence domains
- Significant improvements in score between Pre-Test and PCA observations were measured for all curriculum Learning Objectives
- On the Learning Objective related to distinguishing NAFL from NASH and understanding how to stage the disease, learners retained the gains they achieved during the curriculum on the PCA, with no meaningful change in score from Post-Test to PCA
- On all three other Learning Objectives, scores decreased to near Pre-Test values, from Post-Test to PCA

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

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

4-Week Retention Analysis: Learning Domains



At follow-up:

- A statistically significant net gain was measured from Pre-Test to the Post Curriculum Assessment (PCA) in both Knowledge (17%) and Competence (9%)
- In both Knowledge and Competence, some score slippage was observed between Post-Test and PCA observations

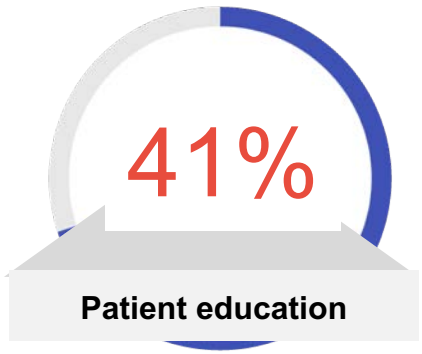
Note: data is matched; learners with a score for the given domain on both the Pre-Test and PCA are included

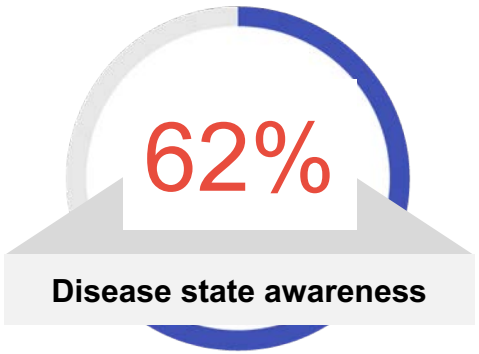
***significant at the p ≤ 0.05 level**

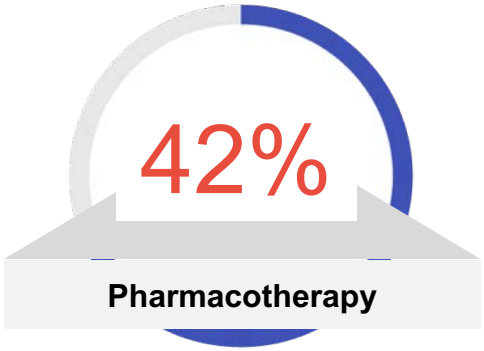
(4-week Post Assessment)

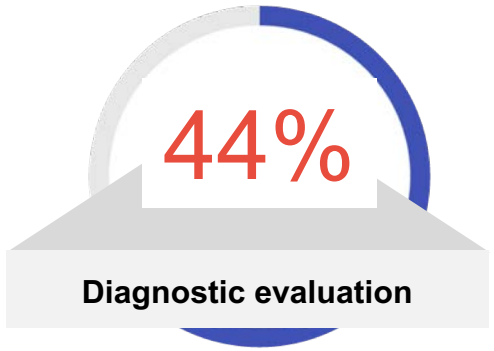
Please select the specific areas of *skills, or practice behaviors*, you have improved regarding the treatment of patients with NASH since this CME activity. (Select all that apply.)

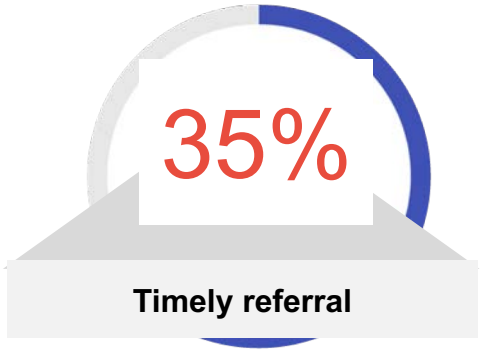
N=225

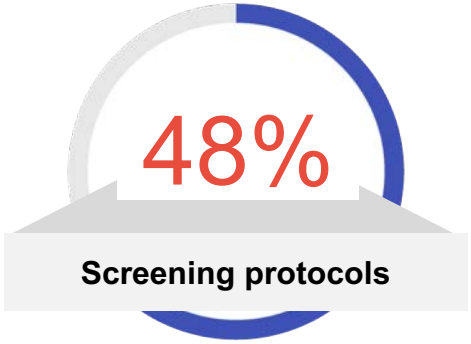


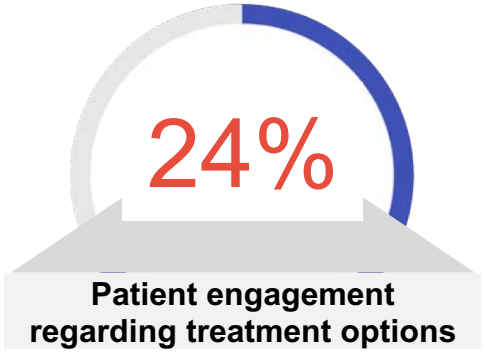








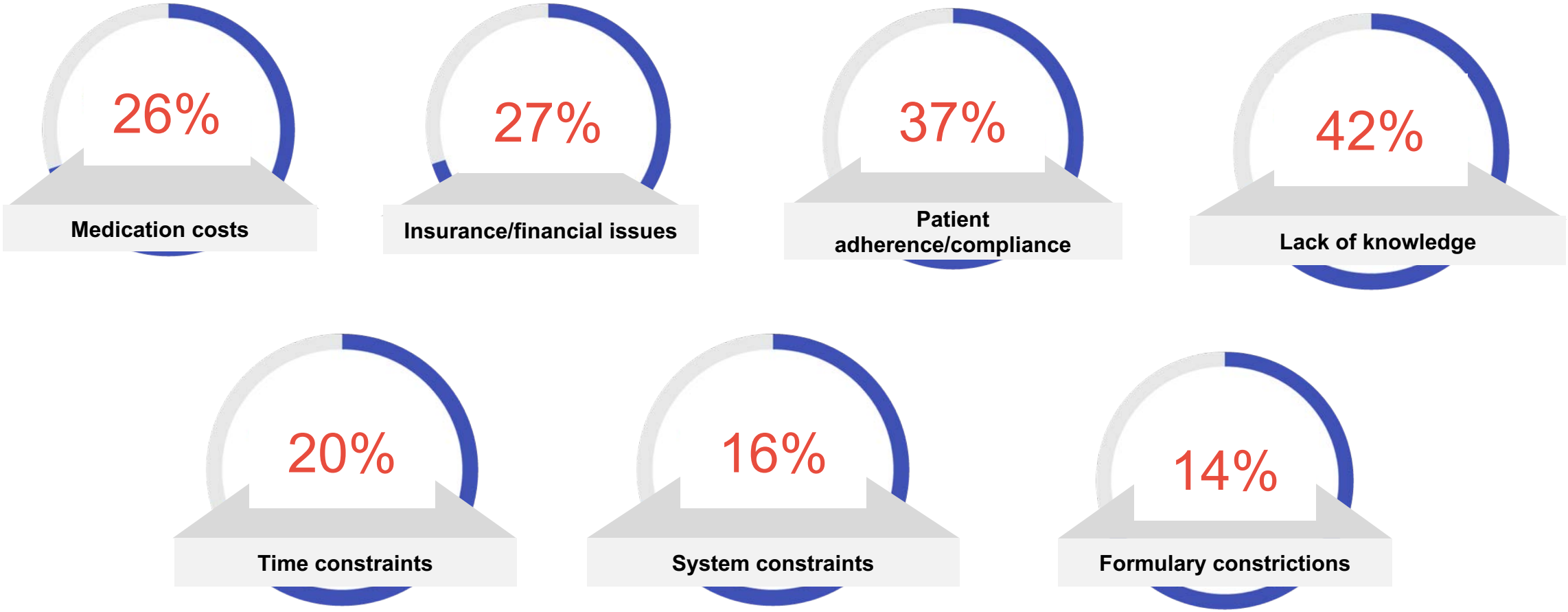




(4-week Post Assessment)

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

N=225



Cohort Comparison by Profession: Learning Objectives

Learning Objective	Nurse Practitioners				Physicians			
	N	Pre-Test	Post-Test	% Change	*N*	Pre-Test	Post-Test	% Change
Identify patients at high risk for nonalcoholic fatty liver disease (NAFLD)	95	13.68% (26.60%)	56.32% (36.45%)	+311.70%*	34	38.24% (36.50%)	77.94% (30.17%)	+103.82%*
Distinguish non - alcoholic fatty liver (NAFL) from nonalcoholic steatohepatitis (NASH) and understand how to stage the disease	93	28.49% (32.29%)	43.55% (38.26%)	+52.86%*	32	50.00% (37.50%)	67.19% (34.48%)	+34.38%*
Implement ongoing evidence - based general management of patients with NASH	94	47.87% (35.67%)	78.19% (35.40%)	+63.34%*	34	57.35% (43.95%)	70.59% (40.43%)	+23.09%*
Describe the available and emerging treatment options for patients with NASH	94	47.87% (35.67%)	78.19% (35.40%)	+63.34%*	34	57.35% (43.95%)	70.59% (40.43%)	+23.09%*

- Nurse practitioners and physicians both achieved substantial and significant improvements in score across all four curriculum Learning Objectives, from Pre- to Post-Test
- Across all four Learning Objectives, nurse practitioners achieved greater score increases compared to physicians, with respect to Pre-Test values

Cohort Comparison by Profession: Learning Domains

Learning Domain	Nurse Practitioners				Physicians			
	N	Pre-Test	Post-Test	% Change	*N*	Pre-Test	Post-Test	% Change
Knowledge	93	39.43% (25.37%)	69.53% (30.78%)	+76.34%*	33	38.89% (35.45%)	79.80% (29.23%)	+105.19%*
Competence	96	26.04% (35.34%)	58.33% (37.27%)	+124.00%*	33	53.03% (38.81%)	65.15% (37.91%)	+22.85%*

- Nurse practitioners and physicians both achieved significant gains from Pre- to Post-Test in both Knowledge and Competence
- Nurse practitioners demonstrated greater improvements from Pre- to Post-Test in Competence, compared to Physicians, while physicians improved more in Knowledge

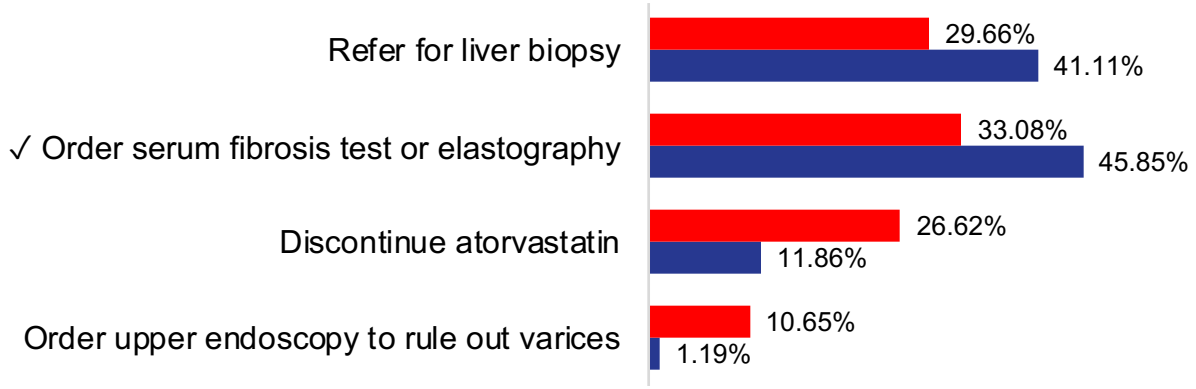
Identified Learning Gap, 1 of 2:
Role of serum fibrosis testing and elastography in diagnosis of liver disease

On a competence item presenting the case of a patient with obesity, type 2 diabetes, ASCVD, hypertension, and dyslipidemia, learners struggled at Post-Test to identify the need to order serum fibrosis test or elastography.

Competence: 58-y/o man with history of obesity, type 2 diabetes, ASCVD, hypertension, and dyslipidemia.
Workup: Elevated ALT (100 U/L), AST (70 IU/L), slightly low platelet count (140 103/microliter) liver edge palpable on exam. A1C is 7.4%. Hepatitis panel is negative. Other findings are WNL. Patient denies any history of alcohol use. Ultrasound of the liver shows increased echogenicity. Which of the following might be an appropriate next step?
Medications: Metformin, linagliptin, atorvastatin, lisinopril.

Results:

- At Post-Test, 46% of learners correctly answered: “Order serum fibrosis test or elastography”



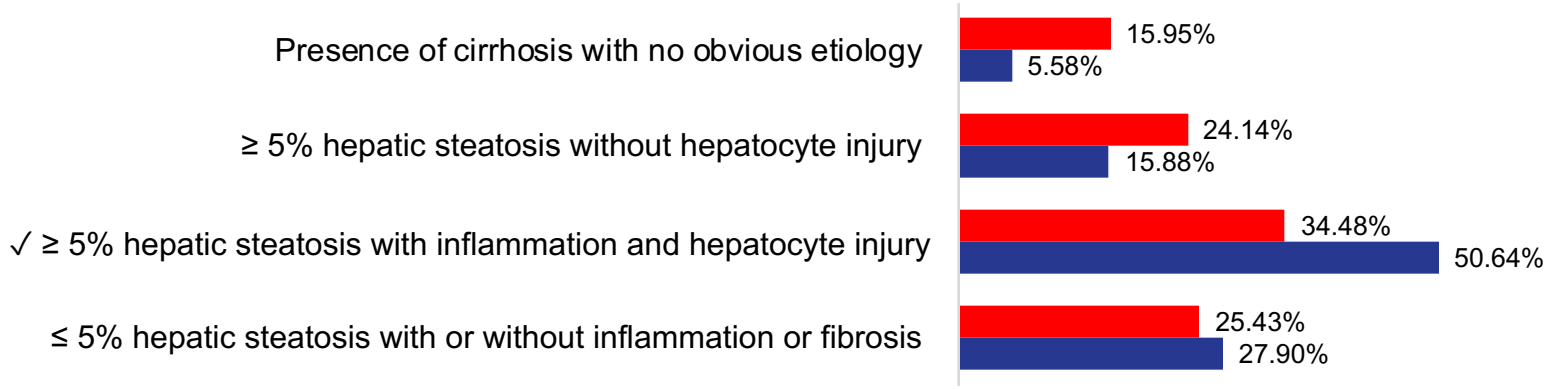
Identified Learning Gap, 2 of 2:
Distinguishing between NASH and other forms of NAFLD

On a Knowledge item discussing criteria distinguishing NASH from other forms of NAFLD, learners struggled to identify the correct response at Post-Test.

Knowledge: Which of the following correctly describes NASH, as compared to other forms of NAFLD?

Results:

- At Post-Test, 51% of learners correctly answered: "≥ 5% hepatic steatosis with inflammation and hepatocyte injury"



Overall Educational Impact

- An increase in score from Pre- to Post-Test was measured in both Knowledge and Competence
  - The strongest improvements in these domains were on items related to racial/ethnic groups at risk for NAFLD (Knowledge), and evidence-based general medical, and non-pharmacologic care, for patients with NASH. (Competence)
  - Significant increases on all curriculum Learning Objectives were 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 (3.58 and 3.61)
- The analysis of scored items in the curriculum identified two **persistent learning gaps related to the role of non-invasive testing in the diagnosis of liver disease, and distinguishing between NASH and other forms of NAFLD**
  - On a Competence item presenting the case of a patient with obesity, type 2 diabetes, ASCVD, hypertension, and dyslipidemia, learners struggled at Post-Test to identify the importance of ordering serum fibrosis testing or elastography
  - Pre- and Post-Test scores were low (34% and 51%) on a Knowledge item asking learners what characteristics distinguish NASH from other forms of NAFLD

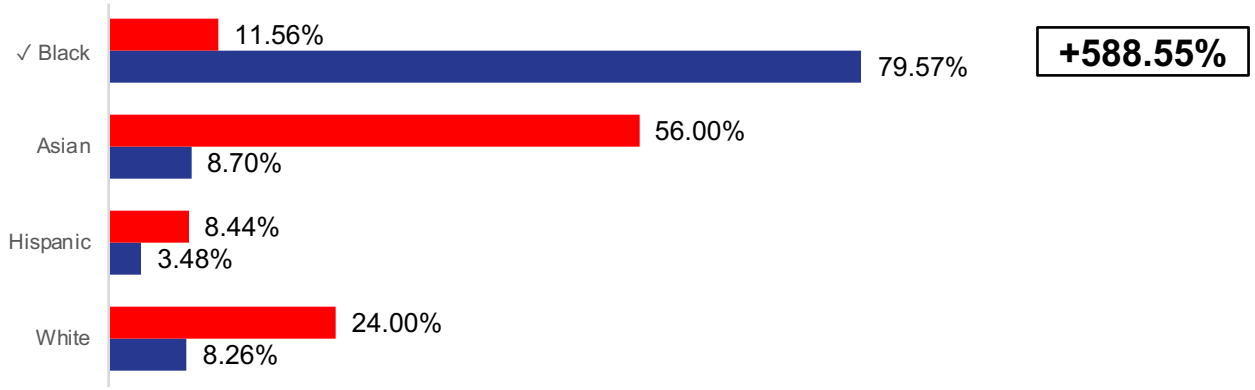
Appendix

Knowledge Items

Pre-Test
Post-Test

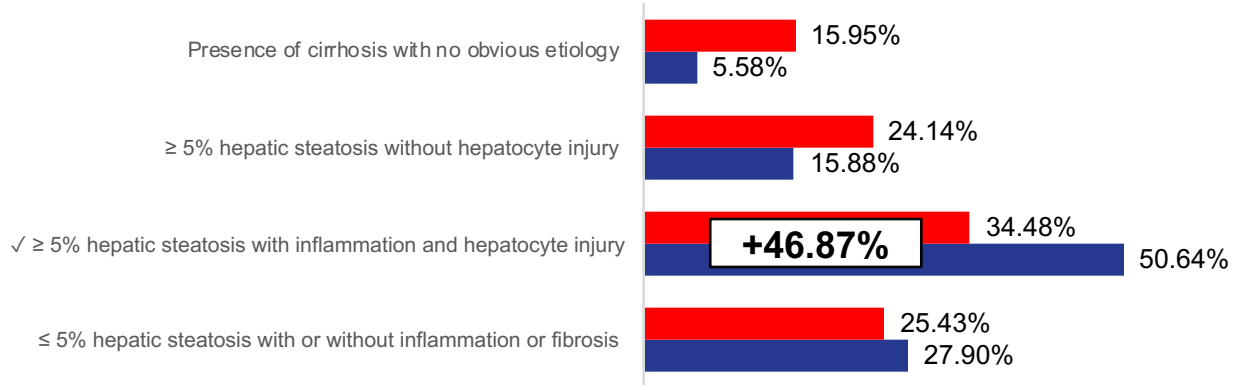
Which of the following racial/ethnic groups has the lowest risk for NAFLD?

N = 225 – 230



Which of the following correctly describes NASH, as compared to other forms of NAFLD?

N = 232 – 233

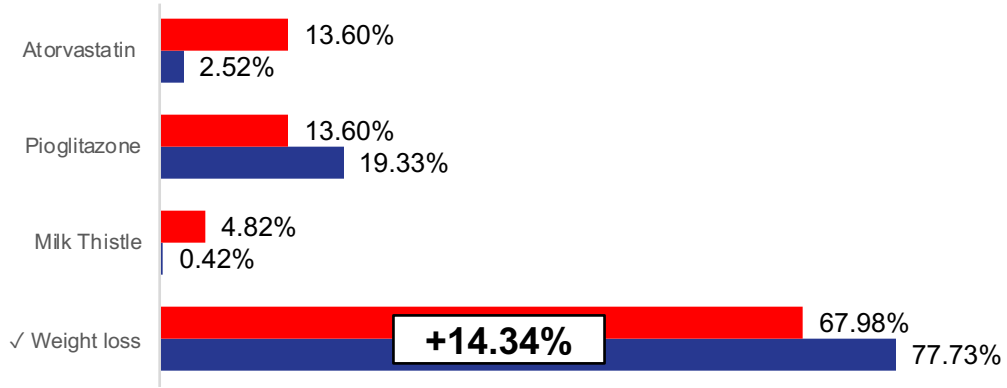


Knowledge Items

Pre-Test
Post-Test

Which of the following has been demonstrated to be most effective at improving the features of NASH and fibrosis?

N = 228 – 238



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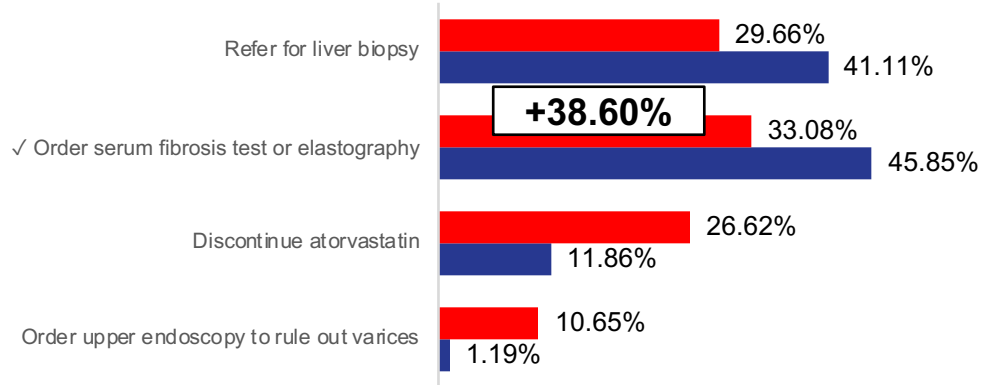
Competence Items

Pre-Test
Post-Test

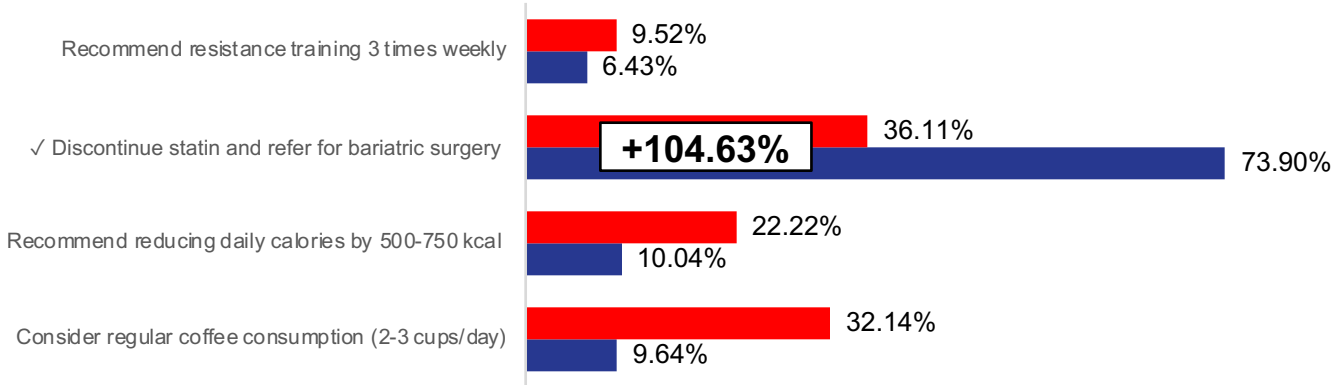
58-y/o man with history of obesity, type 2 diabetes, ASCVD, hypertension, and dyslipidemia.
Workup: Elevated ALT (100 U/L), AST (70 IU/L), slightly low platelet count (140 103/microliter) liver edge palpable on exam. A1C is 7.4%. Hepatitis panel is negative. Other findings are WNL. Patient denies any history of alcohol use. Ultrasound of the liver shows increased echogenicity. Medications: Metformin, linagliptin, atorvastatin, lisinopril. Which of the following might be an appropriate next step?

N = 253 – 263



A 60 y/o obese woman (BMI 32 kg/m2) with a history of elevated LFTs is diagnosed with NASH on biopsy (METAVIR score F2). She also has a history of osteoarthritis, hypertension, dyslipidemia, and prediabetes.
Current medications: Fosinopril/hydrochlorothiazide, rosuvastatin, and naproxen prn. All of the following would be appropriate at this time, EXCEPT:

N = 249 – 252

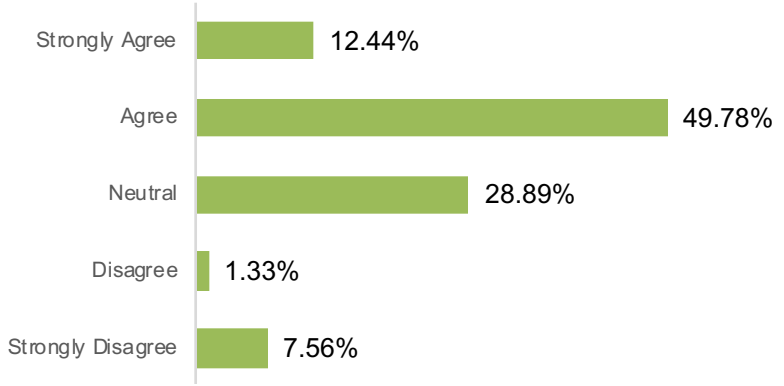


PCA

Confidence items (given at follow-up)

Please rate your level of agreement with the following statement: “I am much more confident in understanding how to perform non-invasive testing for NAFLD.”

N = 225

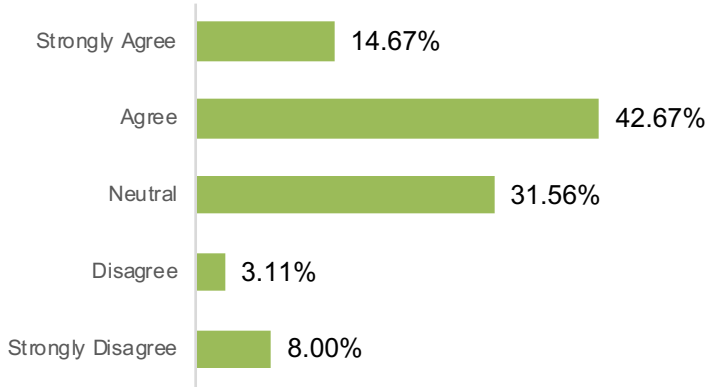


Practice Strategy Items (given at follow-up)

PCA

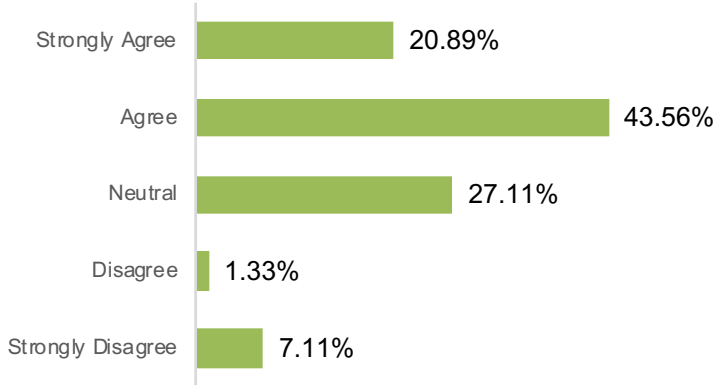
Please rate your level of agreement with the following statement: "I have increased my identification and screening of patients at-risk for NAFLD."

N = 225



Please rate your level of agreement with the following statement: "I more often recommend lifestyle modifications to patients diagnosed with NASH."

N = 225



RealCME

NACE