NACE *Conversations* in Primary Care 2019

Final Live Outcomes Report

Case Studies in Major Depressive Disorder: Individualizing Care

Takeda Pharmaceuticals U.S.A., Inc. and Lundbeck • MED-30654

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September 30, 2019

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NACE *Conversations* in Primary Care 2019

Case Studies in MDD: Individualizing Care

2,382 Participants

3 Activities

1,687 certificates issued to date

This education has the potential to impact **1,164,322** patients with MDD on an annual basis.

20,152–24,630 Patients Weekly

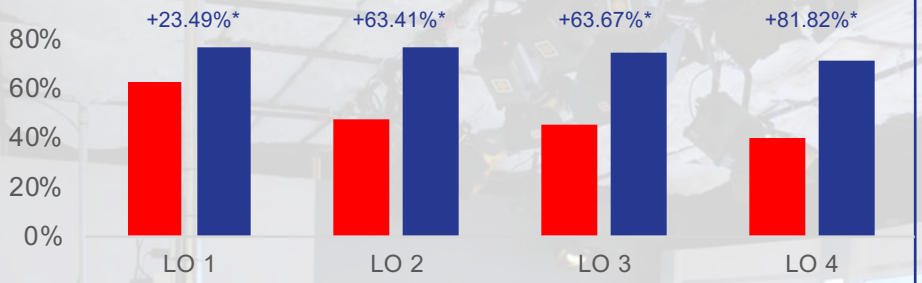
2019 Conversations Activity	Date	Participants
Conversations In Primary Care 2019 Episode 1	2/9/19	867
Conversations In Primary Care 2019 Episode 2	3/2/19	792
Conversations In Primary Care 2019 Episode 3	3/30/19	723
Live Guarantee:1500	**Total**	**2,382**

Enduring Symposium Webcast

Greg Mattingly, MD
Associate Clinical Professor
Department of Psychiatry
Washington University School of Medicine
St. Louis, MO

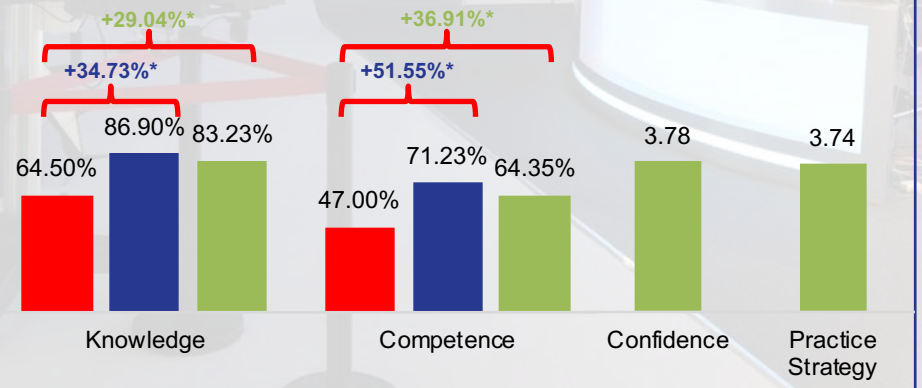
COURSE SUMMARY
Cost: Free
Start Date: 02/19/2019
Expiration Date: 02/18/2020
Target Audience: Primary Care Physicians, Nurse Practitioners, Physician Assistants
Format: Webcast
Estimated Time To Complete CME Activity: 1 hour
Credits: 1.0 AMA PRA Category 1 Credit™; 1.0 AANP Contact hour which includes 0.50 pharmacology hours
Hardware/Software Requirements: Any web browser

Learning Gains Across Objectives



- **LO 1:** Implement measurement - based tools for assessing and monitoring symptoms in patients with MDD
- **LO 2:** Individualize treatment of MDD based on patient presentation, symptom profile and side effects
- **LO 3:** Recognize when switching initial pharmacotherapy is appropriate
- **LO 4:** Incorporate shared decision - making strategies into the management of patients with MDD

Learning Domain Analysis



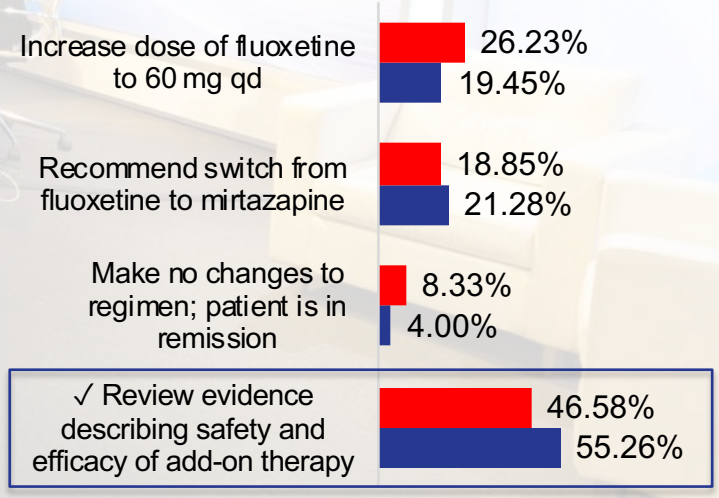
- Learners demonstrated strong, significant improvements from Pre- to Post-Test in Knowledge and Competence
  - High Post-Test scores in Knowledge (91%) were driven by an item on tools for assessing symptoms of MDD, on which learners achieved mastery at Post-Test (96%)
- In Confidence and practice strategy, which were measured at follow-up only, moderate scores were observed

Persistent Learning Gaps/Needs

Modification of therapy for MDD patients not responding fully to existing treatment

On a Competence item presenting the case of a patient with an unchanged PHQ-9 score of 10 in spite of her current pharmacotherapy, learners struggled at Post-Test to accurately identify the need to consider and review appropriate add-on therapy:

A 45-year-old woman with a 2-year history of MDD presents for a checkup. Her PHQ-9 score today is 10, same as her last visit, 6 months ago. On questioning, she notes a persistent lack of energy during the day, but says she otherwise feels good. Current medications include fluoxetine 40 mg qd. Which of the following might be appropriate for this patient?



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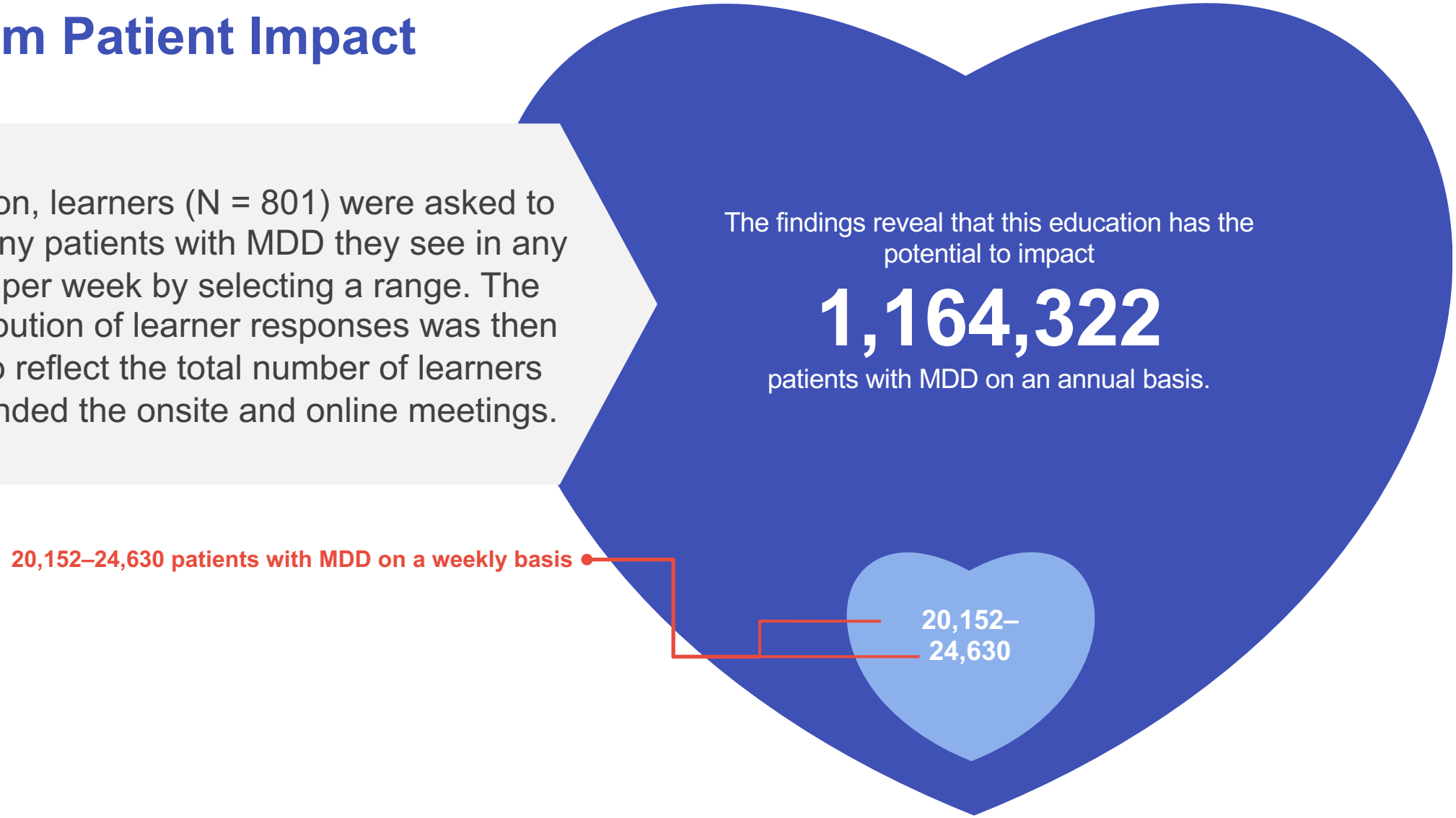
Curriculum Patient Impact

In the evaluation, learners (N = 801) were asked to report how many patients with MDD 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.



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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

- Implement measurement - based tools for assessing and monitoring symptoms in patients with MDD
- Individualize treatment of MDD based on patient presentation, symptom profile and side effects
- Recognize when switching initial pharmacotherapy is appropriate
- Incorporate shared decision - making strategies into the management of patients with MDD

NACE *Conversations* in Primary Care

Curriculum Overview

Three Live Virtual CME Symposia

Enduring CME Symposium Webcast

https://www.naceonline.com/courses/case-studies-in-mdd-individualizing-care

Case Studies in MDD: Individualizing Care

In-Depth Course

Greg Mattingly, MD
Associate Clinical Professor
Department of Psychiatry
Washington University School of Medicine
St. Louis, MO

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COURSE SUMMARY

Cost: Free

Start Date: 02/19/2019

Expiration Date: 02/18/2020

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

Format: Webcast

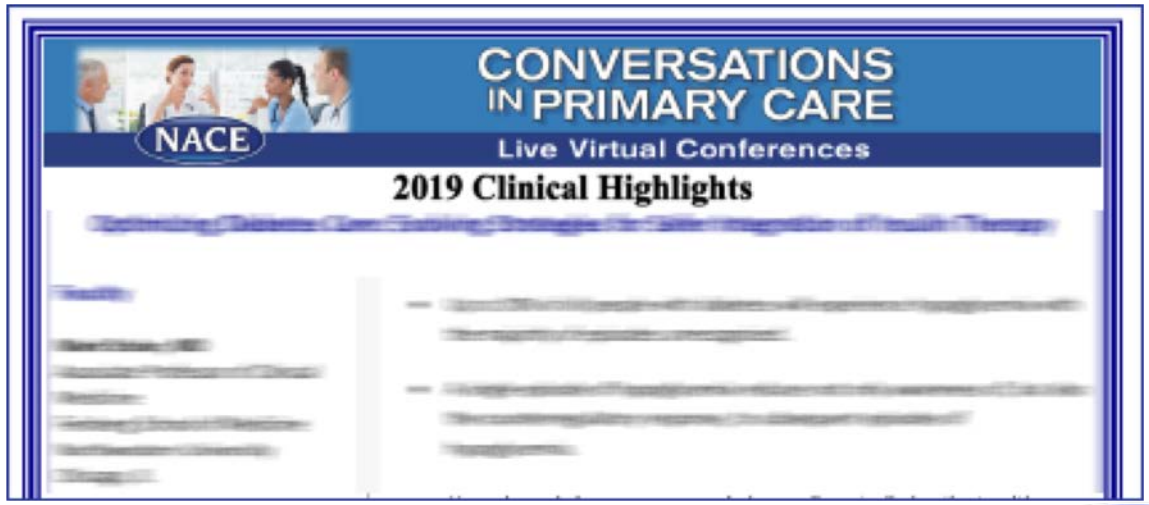
Estimated Time To Complete CME Activity: 1 hour

Credits:
1.0 *AMA PRA Category 1 Credit*™
1.0 AANP Contact hour which includes 0.50 pharmacology hours

Hardware/Software Requirements: Any web browser

Clinical Highlights eMonograph

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



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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

Level 1
Participation
Demographics
Patient Reach

Participation

2,382
Total Attendees

3 Activities

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Participation

2019 Conversations Activity	Date	Participants
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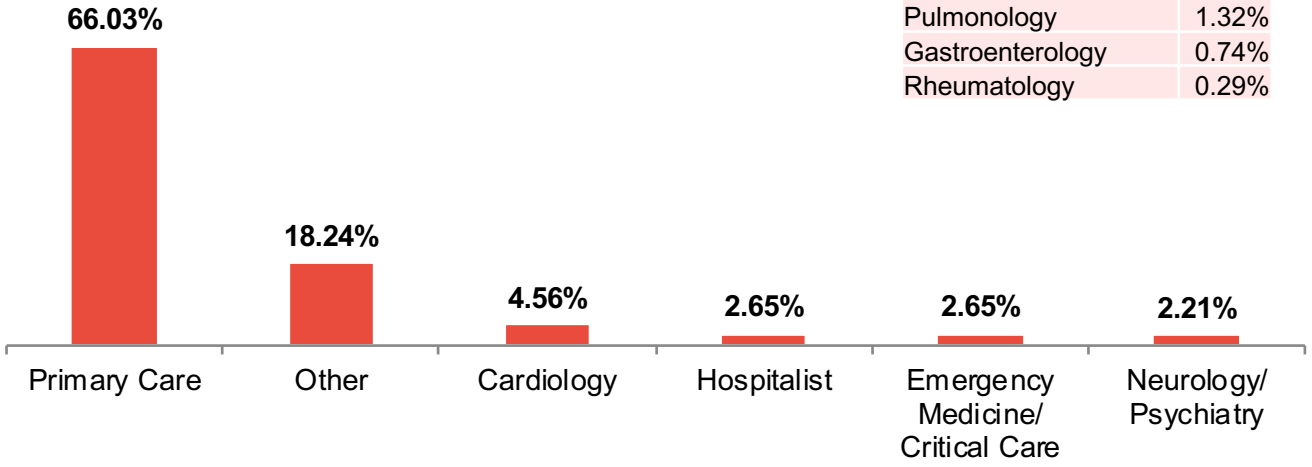
Live Guarantee:1500	**Total**	**2,382**

N = 952

Level 1: Demographics and Patient Reach

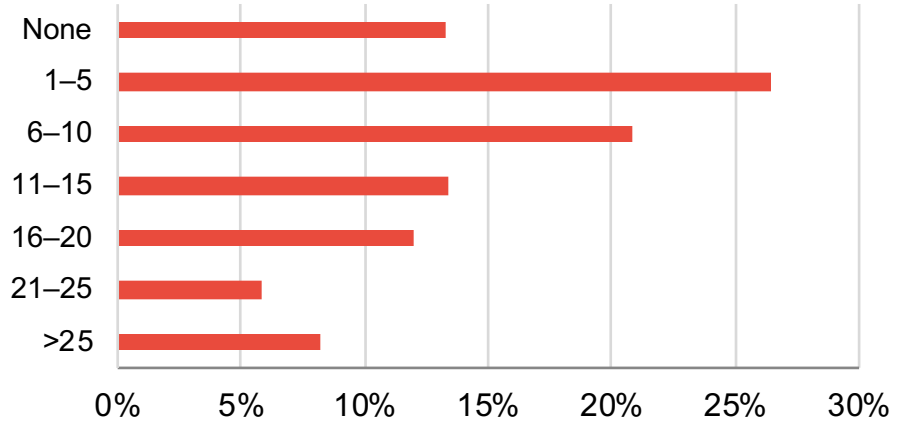
Specialty



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

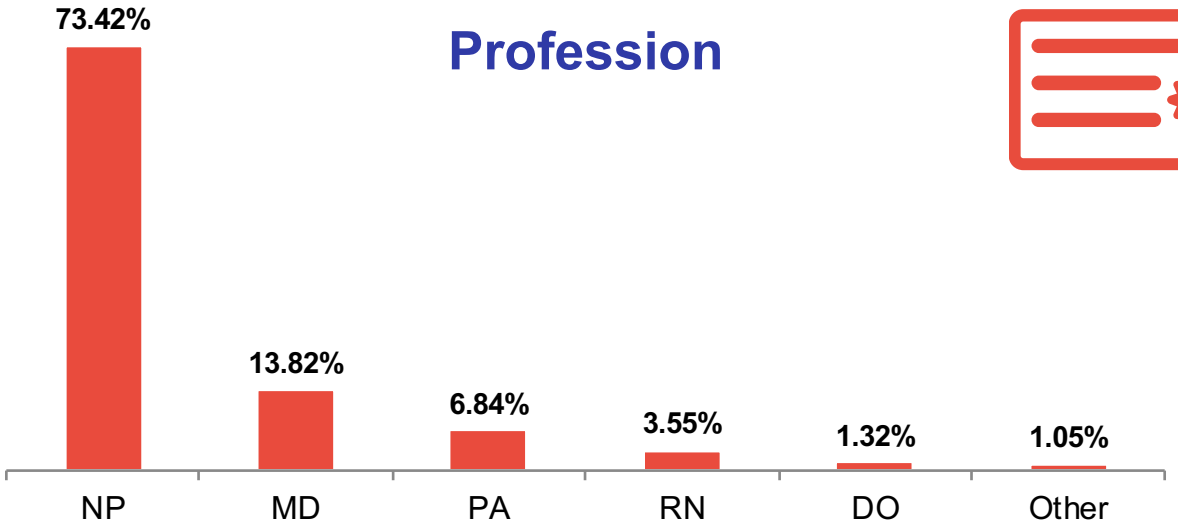
Patient Care Focus: 94%

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

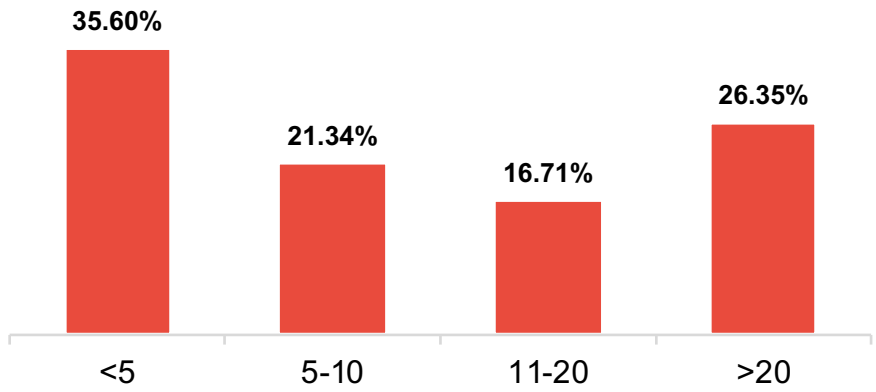


Average number of patients with MDD seen each week per clinician: 10

Profession



Years in Practice



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Level 2-5:
Outcomes Metrics

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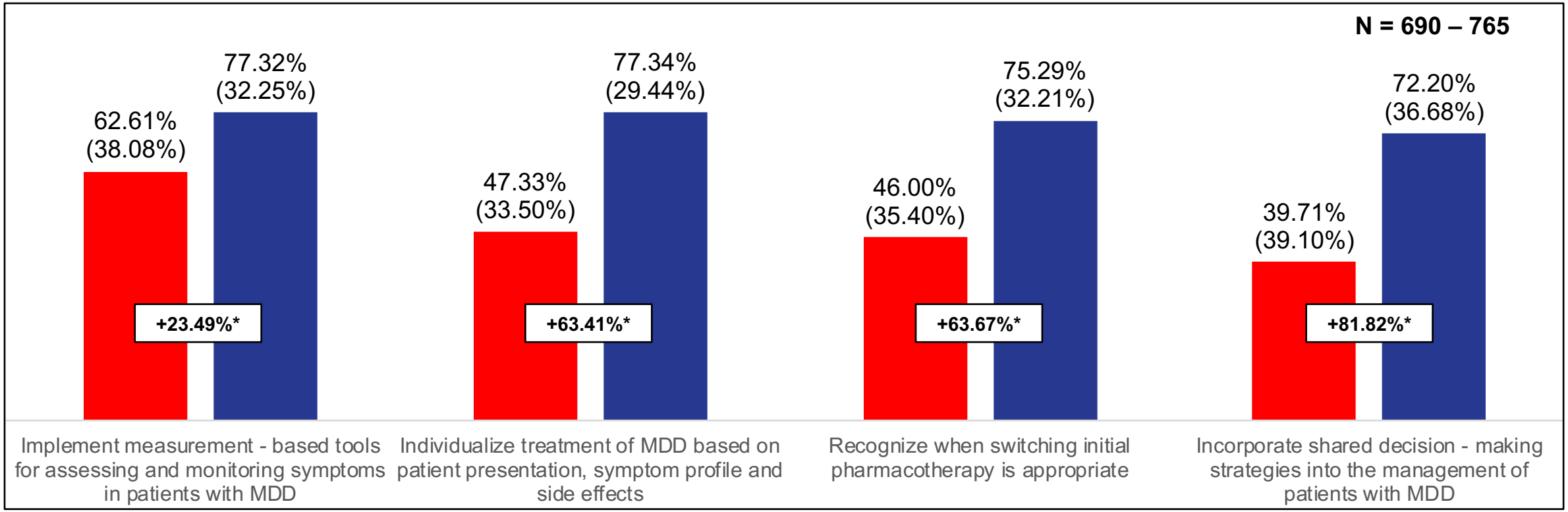
Learning Objective Analysis



- Substantial and significant gains, ranging from 23% to 82%, were retained across all four curriculum learning objectives, from Pre-Test to Post-Test
- Scores on all four Learning Objectives were driven down by a Competence item asking learners to modify therapy for a patient with persistent depression, which was mapped to all four Learning Objectives

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

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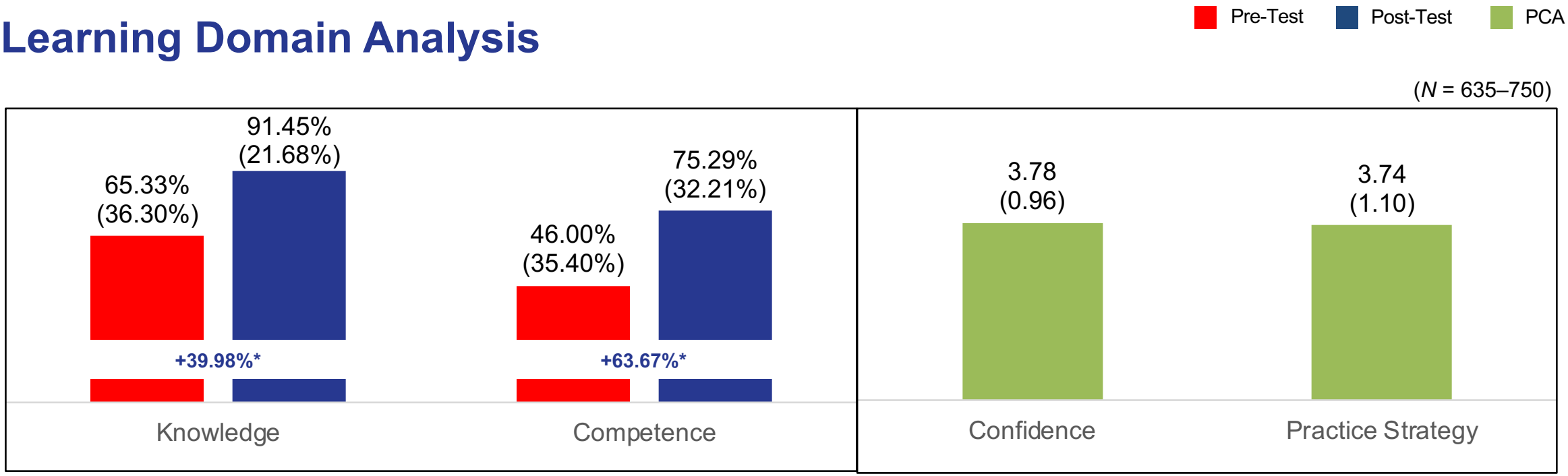
Learning Domain Analysis



- Learners demonstrated strong, significant improvements from Pre- to Post-Test in Knowledge and Competence
  - High Post-Test scores in Knowledge (91%) were driven by an item on tools for assessing symptoms of MDD, on which learners achieved mastery at Post-Test (96%)
  - The most significant increase on a competence question (161%) was driven by the recognition of the appropriateness of switching a patient with MDD from an SSRI to Vortioxetine, due to persistent difficulty concentrating at work and problems with sexual function
  - In Confidence and practice strategy, which were measured at follow-up only, moderate scores were observed

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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***

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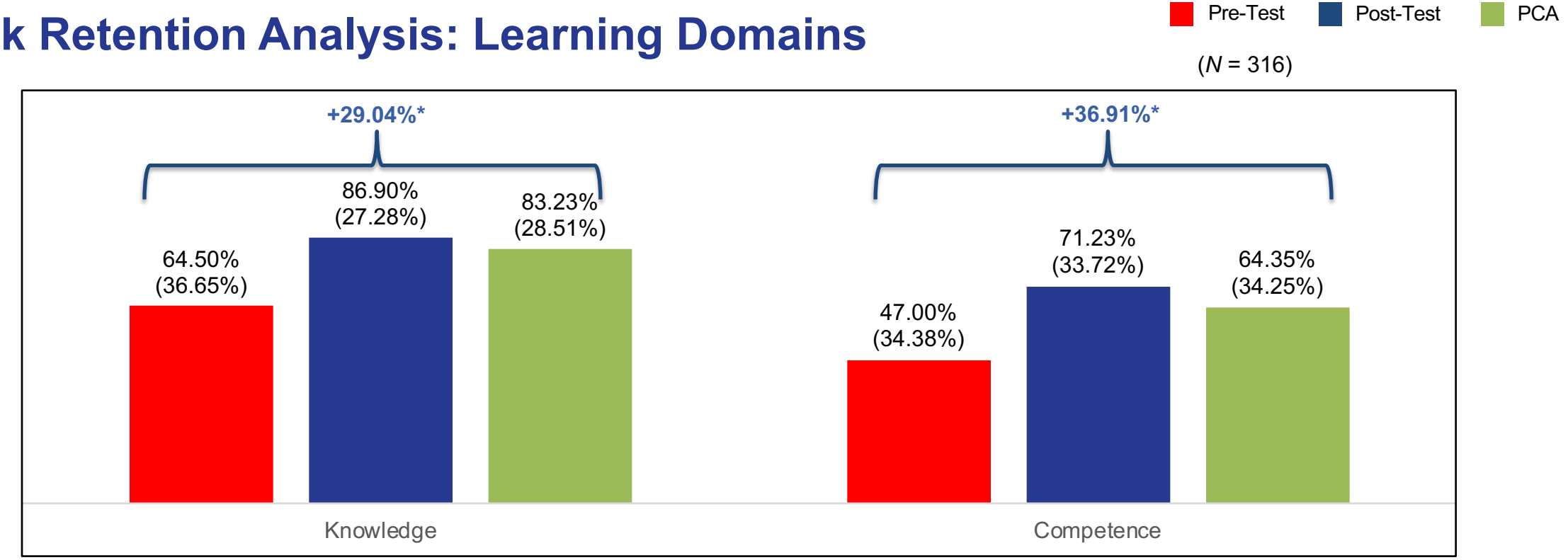
4-Week Retention Analysis: Learning Domains



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 (29%) and Competence (37%)
- Declarative content (Knowledge) was well retained on the PCA, with a small score slippage from Post-Test leaving scores high (83%)

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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**

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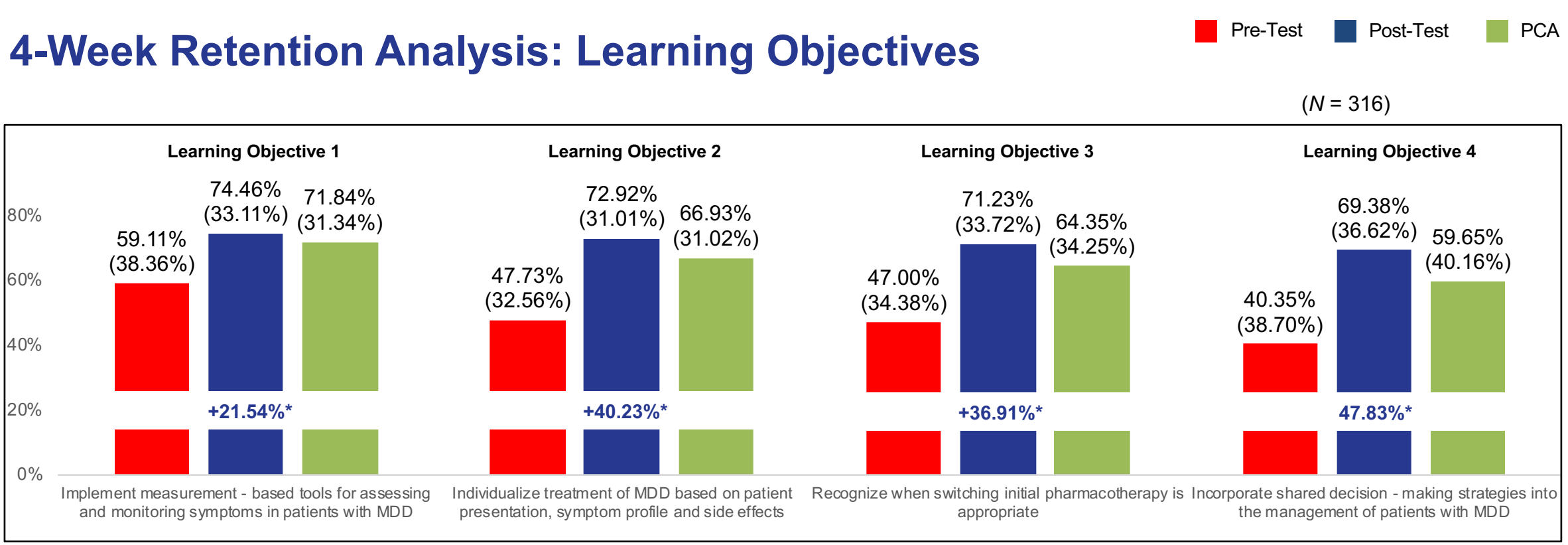
4-Week Retention Analysis: Learning Objectives



- Substantial and significant gains, ranging from 22% to 48%, were retained across all four curriculum learning objectives, from Pre-Test to the PCA
- Across all four curriculum Learning Objectives, moderate Post-Test scores (69% to 74%), combined with score decreases between Post-Test and PCA, resulted in low Post-Test scores (60% to 72%), indicating a need for further reinforcement on this topic

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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**

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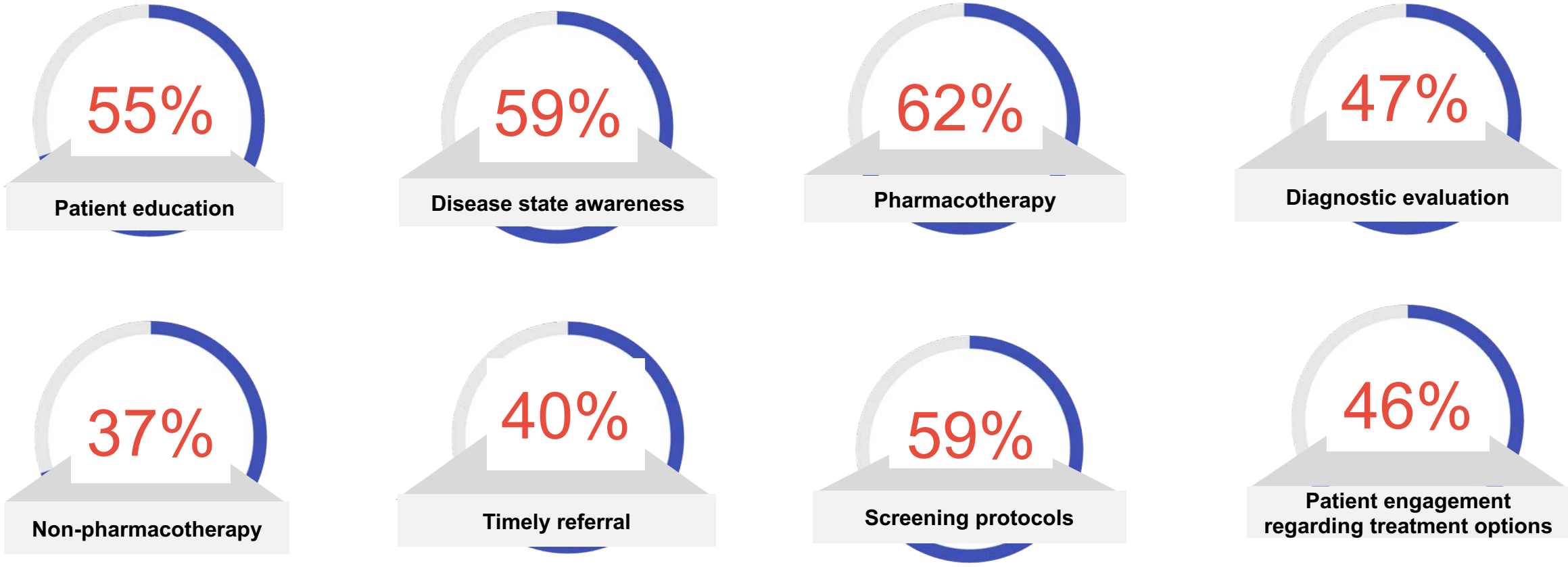
(4-week Post Assessment)

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

N=633

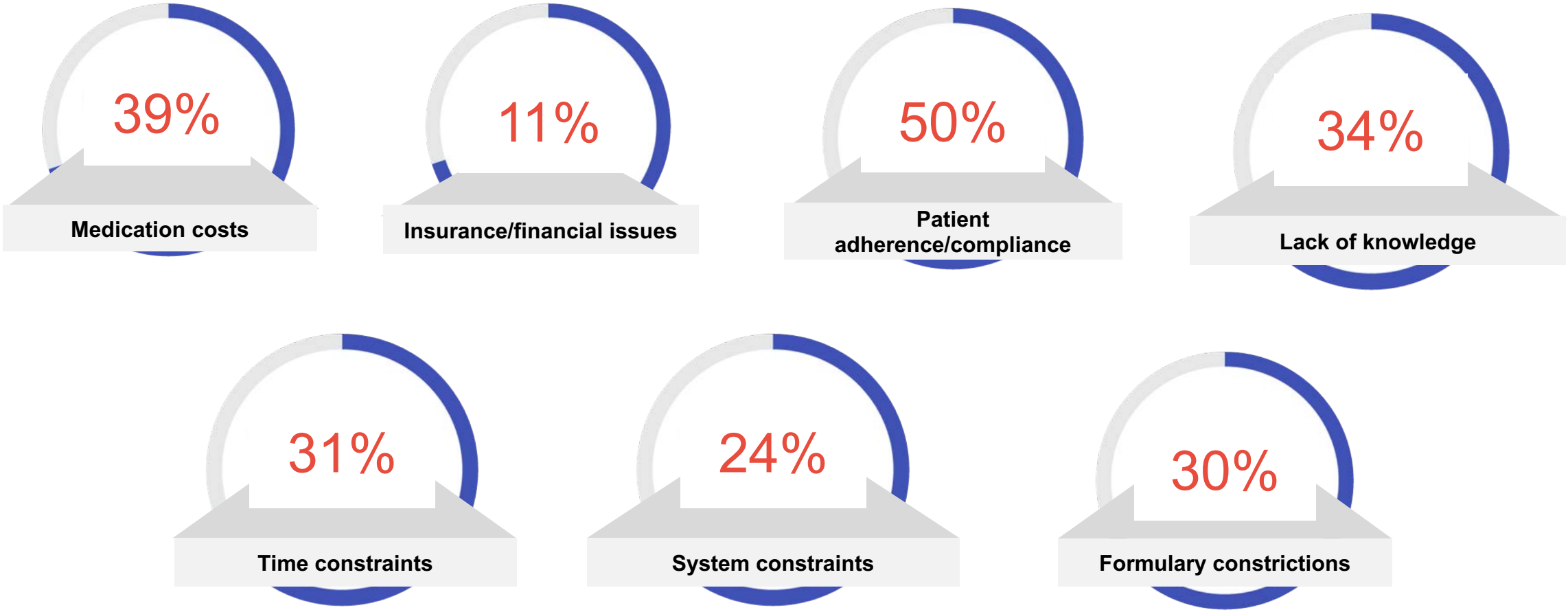


- Learners also reported increased routine use of use of a rating tool, like the PHQ-9, in assessing patients for depression and increased the frequency with which they ask patients about their treatment preferences for depression.

(4-week Post Assessment)

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

N=633



Cohort Comparison by Profession: Learning Objectives

Learning Objective	Nurse Practitioners				Physicians			
	N	Pre-Test	Post-Test	% Change	*N*	Pre-Test	Post-Test	% Change
Implement measurement - based tools for assessing and monitoring symptoms in patients with MDD	328	63.11% (36.98%)	77.74% (30.87%)	+23.18%*	72	62.50% (37.03%)	79.86% (29.65%)	+27.78%*
Individualize treatment of MDD based on patient presentation, symptom profile and side effects	350	45.93% (32.95%)	78.29% (27.85%)	+70.46%*	82	53.66% (34.53%)	81.30% (27.66%)	+51.51%*
Recognize when switching initial pharmacotherapy is appropriate	346	44.36% (35.36%)	76.30% (31.04%)	+72.00%*	79	55.27% (35.73%)	79.32% (29.79%)	+43.51%*
Incorporate shared decision - making strategies into the management of patients with MDD	335	38.66% (38.51%)	73.13% (35.54%)	+89.16%*	76	50.00% (42.15%)	76.32% (34.86%)	+52.64%*

- Substantial and significant gains on all four Learning Objectives were measured for both nurse practitioners and physicians, from Pre- to Post-Test
- Physicians had moderately higher Pre- and Post-Test scores compared to nurse practitioners, for all four curriculum Learning Objectives

Cohort Comparison by Profession: Learning Domains

Learning Domain	Nurse Practitioners				Physicians			
	N	Pre-Test	Post-Test	% Change	*N*	Pre-Test	Post-Test	% Change
Knowledge	308	67.05% (34.09%)	91.23% (21.42%)	+36.06%*	70	60.71% (40.44%)	95.00% (15.00%)	+56.48%*
Competence	346	44.36% (35.36%)	76.30% (31.04%)	+72.00%*	79	55.27% (35.73%)	79.32% (29.79%)	+43.51%*

- Both nurse practitioners and physicians increased their Knowledge and Competence scores significantly, from Pre-Test to Post-Test
- Physicians had higher Pre- and Post-Test scores in both Knowledge and Competence, compared to nurse practitioners

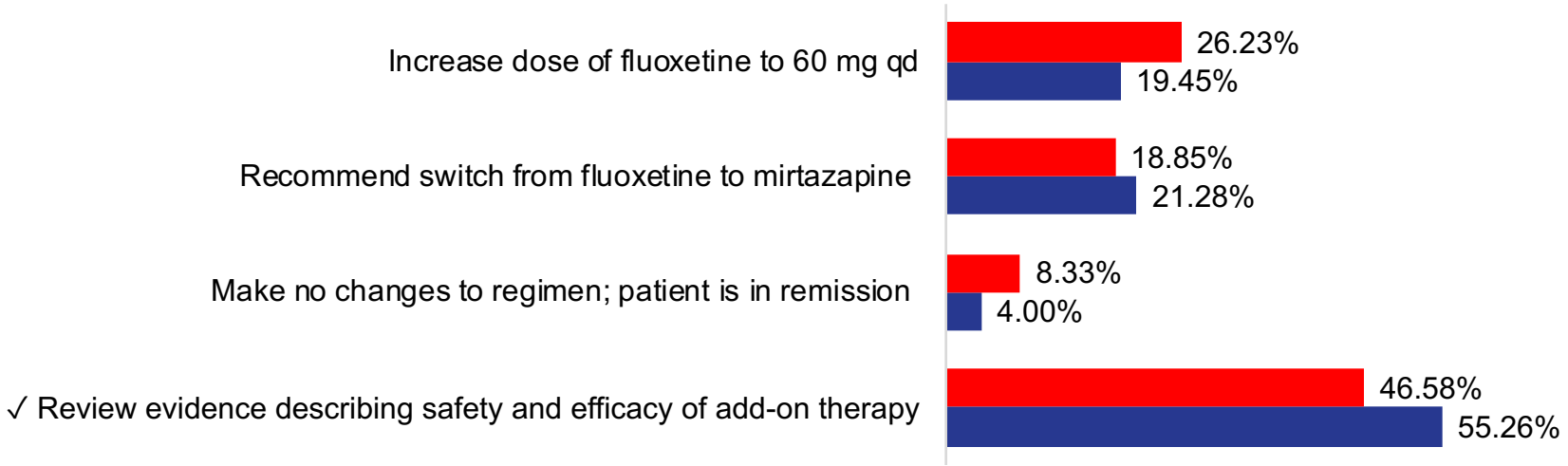
Identified Learning Gap:
Modification of therapy for MDD patients not responding fully to existing treatment

On a Competence item presenting the case of a patient with an unchanged PHQ-9 score of 10 in spite of her current pharmacotherapy, learners struggled at Post-Test to accurately identify the need to consider and review appropriate add-on therapy:

Competence: A 45-year-old woman with a 2-year history of MDD presents for a checkup. Her PHQ-9 score today is 10, same as her last visit, 6 months ago. On questioning, she notes a persistent lack of energy during the day, but says she otherwise feels good. Current medications include fluoxetine 40 mg qd. Which of the following might be appropriate for this patient?

Results:

- At Post-Test, only 55% of learners correctly answered: “Review evidence describing safety and efficacy of add-on therapy”



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Overall Educational Impact

- Significant improvements (of 40% and 64%) were seen in both Knowledge and Competence items
  - Moderate Post-Test scores (75%) were measured in Competence, with high (91%) Post-Test scores in Knowledge
    - This low average Competence score was driven by poor Post-Test scores on an item presenting the case of a patient with MDD not responding fully to her current therapy
  - Final scores on Confidence and practice strategy questions were moderate (3.78 and 3.74)
- Substantial and significant improvements ranging from 23% to 82% were measured across all Learning Objectives, from Pre-Test to Post-Test.
  - Post-Test Learning Objective scores remained moderate (72% to 77%), driven by the previously mentioned Competence item, mapped to all four objectives
- The analysis of scored items in the curriculum identified a **persistent learning gap related to modification of therapy for MDD patients not responding fully to existing treatment**
  - Pre- and Post-Test scores (47% and 55%) were low on a Competence item addressing treatment decisions for a patient presenting with an elevated PHQ-9 score in spite of her current antidepressant therapy
- Future educational activities should focus on helping providers how to individualize therapy for MDD, and recognize when and how to switch therapies.

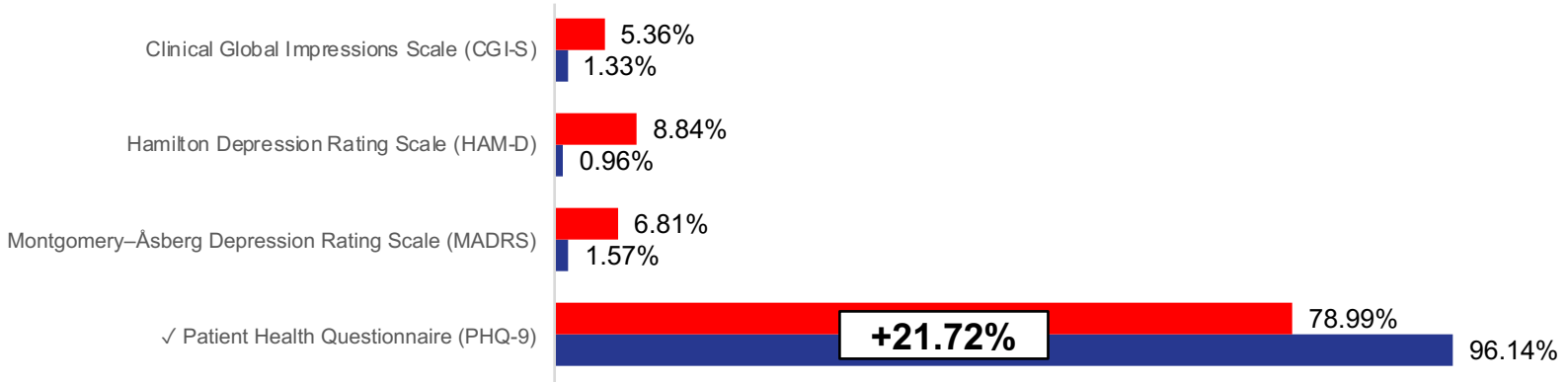
Appendix

Knowledge Items

Pre-Test
Post-Test

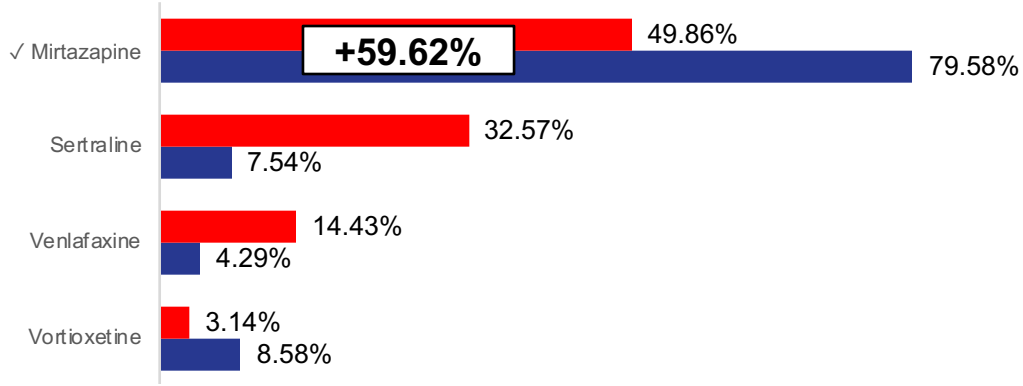
Which of the following tools is well suited to assessing MDD symptoms in routine primary care settings?

N = 690 – 830



Which of the following antidepressants may help to improve sleep and appetite in a patient with MDD?

N = 700 – 862



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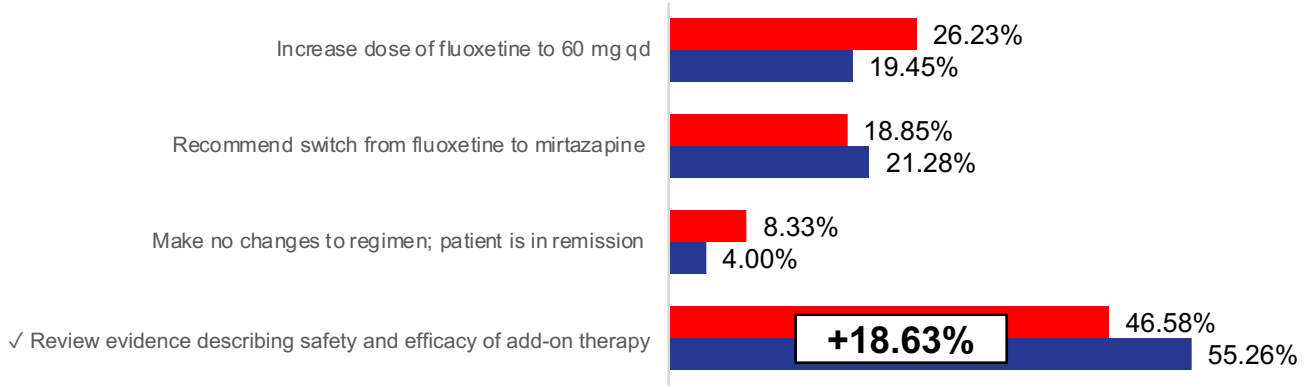
Competence Items

Pre-Test
Post-Test

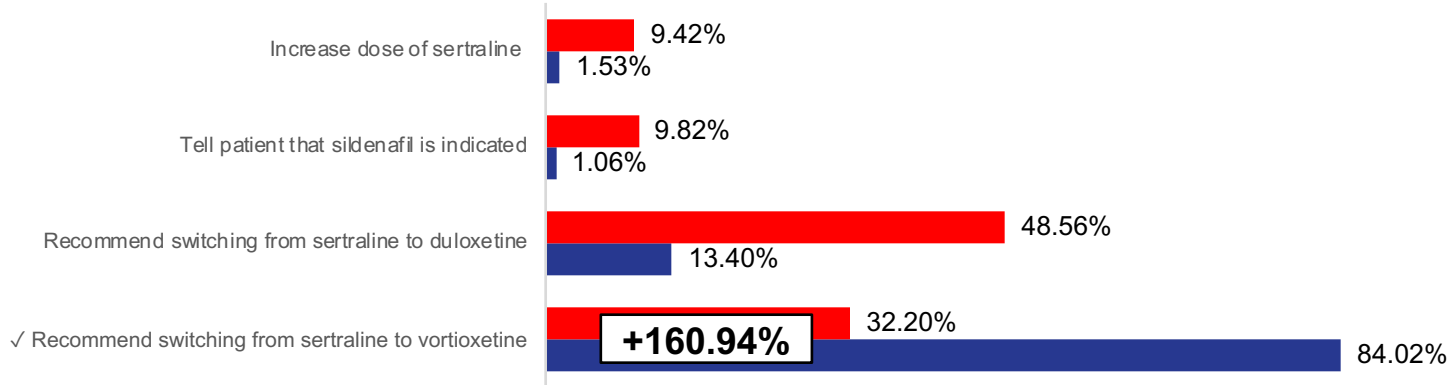
A 45-year-old woman with a 2-year history of MDD presents for a checkup. Her PHQ-9 score today is 10, same as her last visit, 6 months ago. On questioning, she notes a persistent lack of energy during the day, but says she otherwise feels good. Current medications include fluoxetine 40 mg qd. Which of the following might be appropriate for this patient?

N = 732 – 874



A 31-year-old man is diagnosed with moderate-severe MDD. At diagnosis, he reports anhedonia, loss of appetite, and frequent missed work days. Treatment with sertraline 50 mg qd is started. Over 6 months, his depressive symptoms improve and he resumes normal daily activities. At his next checkup, he reports persistent difficulty concentrating at work and problems with sexual function. Which of the following might be appropriate for this patient?

N = 764 – 851



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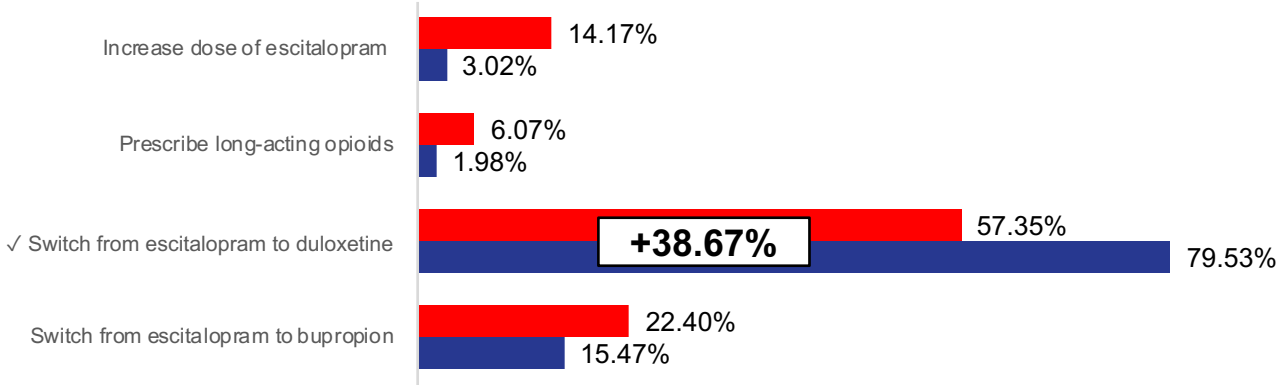
Competence Items

A 67-year-old woman with a 2-year history of MDD and 4-year history of chronic low back pain presents for a checkup. Her PHQ-9 score is 11 (moderate), unchanged from her prior visit. During discussion, she notes that the back pain affects her mood and daily function. Current medications include escitalopram 20 mg qd. Which of the following might be appropriate for this patient?

N = 741 – 860

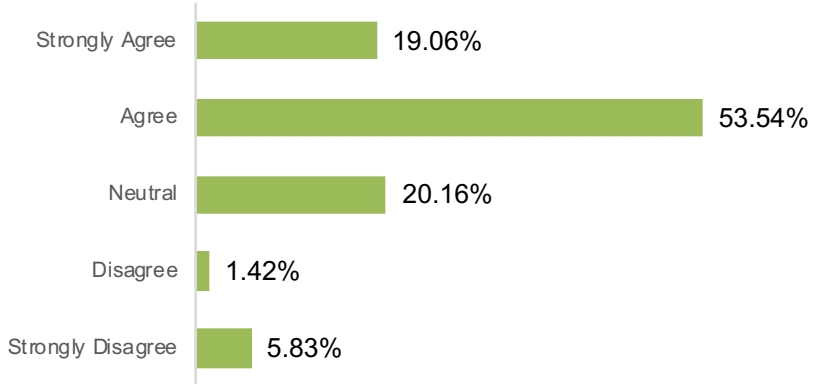


Confidence items (given at follow-up)

PCA

Please rate your level of agreement with the following statement: "I am more confident in tailoring antidepressant therapy to individual patients' needs."

N = 635



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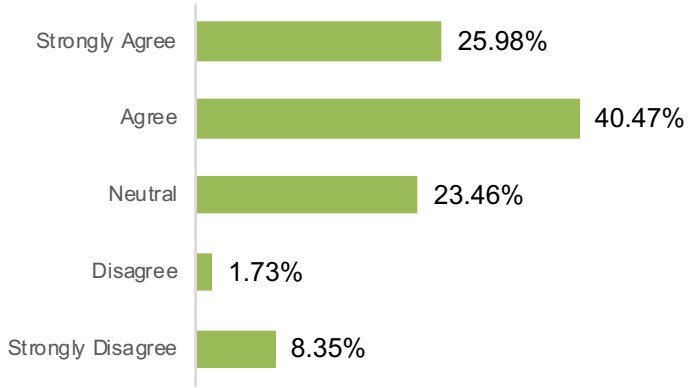
Practice Strategy Items (given at follow-up)

PCA

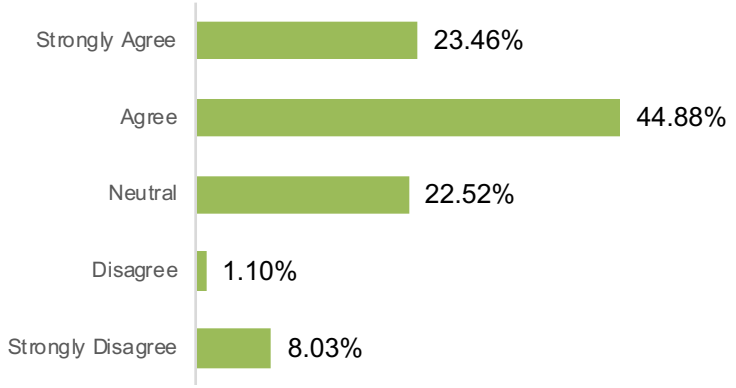
Please rate your level of agreement with the following statement: "I have increased my use of a rating tool, like the PHQ-9, in assessing patients for depression."

N = 635



Please rate your level of agreement with the following statement: "I have significantly increased the frequency with which I ask patients about their treatment preferences for depression."

N = 635



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