Integrating Data on Macrovascular and Microvascular Outcomes into Diabetes Management: Evolving Treatment Strategies

Final Outcomes Report

April 5, 2018

Boehringer Ingelheim-Lilly USA Grant ID: ME 201621692

RealCME

NACE

Executive Summary

Participants demonstrated significant improvement in:

- Recognition of the role of the kidney in glucose metabolism
- Awareness of the efficacy of SGLT-2 therapy
- Understanding of current data on the renal and vascular impact of diabetes treatments
- Ability to incorporate treatment decisions to minimize hypoglycemia
- Intent to modify antidiabetic therapy based on risk for hypoglycemia after the program
- Their confidence (46% improvement) in their ability to select patients appropriate for treatment with SGLT-2 inhibitors.

4335 Total Attendees

18 Cities

2731 On Site

1604 Remote Simulcast

Pre to Post Test Results By Learning Objective

#	Learning Objective (*N* = 2,707)	Pre-Test	Post-Test	% Change
1	Describe the role of the kidney in glucose metabolism in health and disease	18.77%	51.20%	**172.78%***
2	Review the physiologic effects and clinical efficacy of SGLT-2 therapy in various patient populations	60.74%	72.94%	**20.09%***
3	Review emerging data on possible renal and macrovascular effects of evidence-based diabetes treatment options	60.42%	74.71%	**23.65%***
4	Integrate the impact of treatment decisions on postprandial hyperglycemia and risk of hypoglycemia	60.42%	74.71%	**23.65%***

* Results are statistically significant $p < .05$

Emerging Challenges in Primary Care
Update 2017

Curriculum Patient Impact

Onsite and Simulcast Participant Performance

- Both Live meeting and Simulcast cohorts increased their Pre-Test scores and performed similarly by Post-Test on all domains
- There was no significant difference in the improvement each cohort achieved demonstrating the equality of the impact that each delivery modality

4 Week Post-Activity Assessment

- 4 weeks after the live activity, participants reported the most significant improved abilities in their management of:
  - Pharmacotherapy
  - Disease state awareness
  - Patient education

Persistent Educational Gaps

- Learners were challenged by treatment intensification as well as the role of the kidney in glucose reabsorption
- There is need for ongoing educational emphasis on SGLT2 inhibitor efficacy
- There is need for ongoing educational emphasis on role of the kidneys in glucose metabolism.

In the CME evaluation, learners (N = 3,329) were asked to report how many patients with diabetes they see in any clinical setting per week by selecting a range. The resulting distribution of learner responses was then extrapolated to reflect the number of learners who have completed the content of the meetings.

Curriculum Overview

- Accredited Live Regional Symposia
  - Launch Date: April 29, 2017 through January 20, 2018
  - The live symposium was held in 18 cities with national simulcasts from 6 cities.

- Interactive Enduring Activity
  - Launch Date: October 12, 2018 End Date: October 13, 2019
  - http://naceonline.com/CME-Courses/course_info.php?course_id=923

- Non-Accredited “Clinical Highlights”
  - Emailed to all participants within one week of each symposia
  - Reinforces content to participants
  - Contains clinical pearls to assist clinicians with the application of the education to practice

Learning Objectives

1. Describe the role of the kidney in glucose metabolism in health and disease
2. Review the physiologic effects and clinical efficacy of SGLT-2 therapy in various patient populations
3. Review emerging data on possible renal and macrovascular effects of evidence-based diabetes treatment options
4. Integrate the impact of treatment decisions on postprandial hyperglycemia and risk of hypoglycemia

Faculty and Planning Committee

Course Director

Gregg Sherman, MD
Chief Medical Officer of NACE
Plantation, FL

Activity Planning Committee

Gregg Sherman, MD

Harvey C. Parker, PhD, CHCP

Michelle Frisch, MPH, CHCP

Stephen Webber

Alan Goodstat, LCSW

Sheila Lucas, CWEP

Faculty

Richard S. Beaser, MD
Senior Staff Physician,
Medical Director of Professional Education
Joslin Diabetes Center
Associate Clinical Professor of Medicine
Harvard Medical School
Boston, MA

Robert S. Busch, MD, FACE
Director of Clinical Research
Albany Medical Faculty: Community Endocrine Group
Albany, NY

Mark Stolar, MD
Associate Professor of Clinical Medicine
Feinberg School of Medicine
Northwestern University
Chicago, IL

Richard Pratley, MD
Senior Investigator and Diabetes Program Head
Translational Research Institute for Metabolism and Diabetes
Research and Education Director,
Florida Hospital Diabetes Institute
Orlando, FL

Jeff Unger, MD, ABFM, FACE
Director, Unger Primary Care Medical Group
Rancho Cucamonga, CA

Outcomes Assessment Methodology

ACTIVITY PROTOCOL

- Data collection:
  - Paired **Pre- and Post-Test** questions
  - **Demographic** questions
  - Learner **Challenge** questions
- Employs **Knowledge, Competence, Confidence**, and **practice strategy** question types
- Appropriate statistics applied to assess change across learning domains

CURRICULUM OUTCOMES PROTOCOL

- Assess Moore's Levels 1–5
- **Learning objective** analysis
- **Longitudinal** analysis following learner scores over monthly intervals (e.g., learning objectives, domains, repeated measure)
- Multi-dimensional **repeated-measure** (Level 5):
  - Prior to activity/after completion of each activity
  - Post-curriculum assessment survey

Outcomes Assessment Methodology

Activity Outcomes Protocol Measures Moore's Levels 1-4	**Curriculum Outcomes Protocol** Measures Moore's Levels 1-5
Learning Domain Question Types • Knowledge • Competence • Confidence • Practice Strategy	RealIndex® Question • Prior to activity • Post activity • Post Curriculum Assessment (PCA)

Attendance and Engagement

#	Meeting/Simulcast Location (Date)	Attendees	Starts	Content Completion	
1	Miami Live Meeting (04/29)	190	176	152	86.36%
2	Baltimore Live Meeting (05/06)	186	184	149	80.98%
3	St. Louis Live Meeting (05/13)	114	97	91	93.81%
4	Birmingham Live Meeting (05/20)	150	145	128	88.28%
5	Birmingham Simulcast (S,05/20)	222	221	122	55.20%
6	Atlanta Live Meeting (06/03)	240	211	198	93.84%
7	Raleigh Live Meeting (06/10)	130	121	112	92.56%
8	Raleigh Simulcast (S, 06/10)	322	175	98	56.00%
9	Cleveland Live Meeting (06/17)	66	62	58	93.55%
10	Tampa Live Meeting (06/24)	267	228	214	93.86%
11	Anaheim Live Meeting (08/12)	175	151	128	84.77%
12	Anaheim Simulcast (S, 08/12)	155	111	54	48.65%
13	San Francisco Live Meeting (08/19)	84	78	70	89.74%
14	Troy Live Meeting (08/26)	244	192	171	89.06%
15	Troy Simulcast (S, 08/26)	307	221	114	51.58%
16	San Antonio Live Meeting (09/23)	105	97	88	90.72%
17	Uniondale Live Meeting (10/17)	309	226	196	86.73%
18	Nashville Live Meeting (10/14)	110	110	80	72.72%
19	Nashville Simulcast (S, 10/14)	219	165	56	33.93%
20	Houston Live Meeting (10/21)	132	132	95	71.97%
21	San Diego Live Meeting (10/28)	112	112	85	75.89%
22	San Diego Simulcast (S, 10/28)	379	234	121	51.74%
	Total	**4,335**	**3,634**	**2,763**	**76.03%**

Attendee: Registrants Start: Answered at Least One Question Content Completion: Completed the Post-Test

RealCME

NACE

Level 1:
Participation &
Demographics

Emerging Challenges in Primary Care
Update 2017

Level 1 (Participation)

4,335
Total Attendees

18 Cities

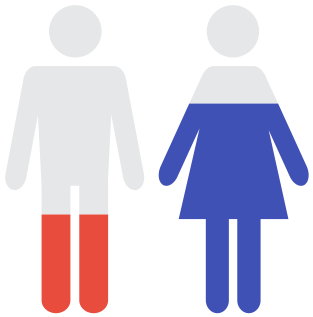
2731
On Site

1604
Remote Simulcast

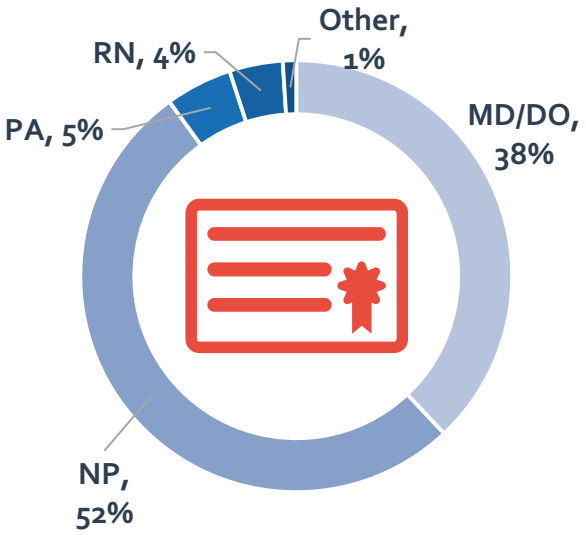
Level 1: Demographics

Patient Care Focus – Yes: 92% **No: 8%**

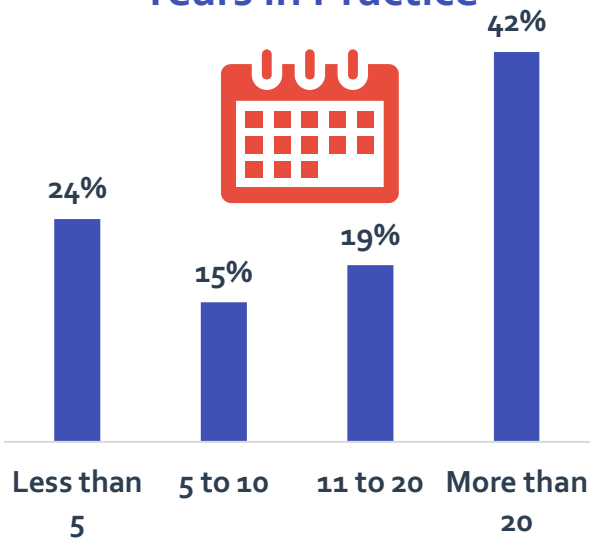
Gender



Profession



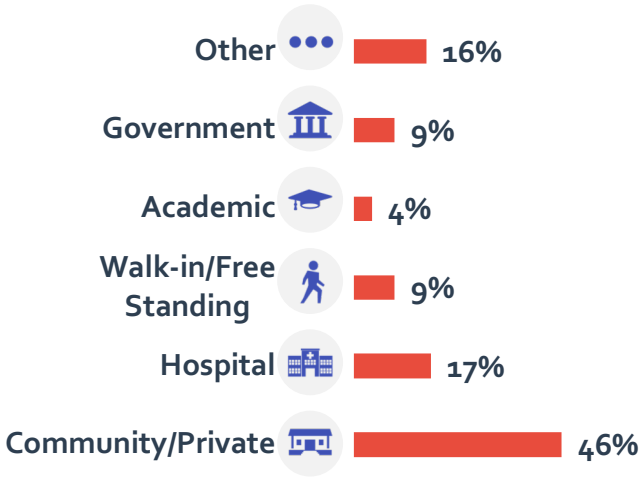
Years in Practice



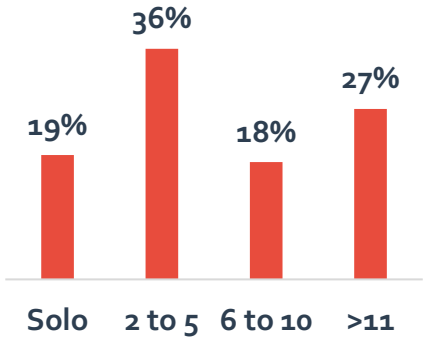
Emerging Challenges in Primary Care
Update 2017

Level 1: Demographics

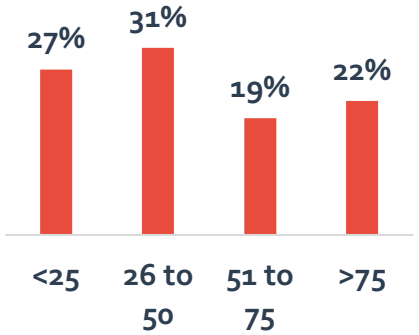
Type of Practice



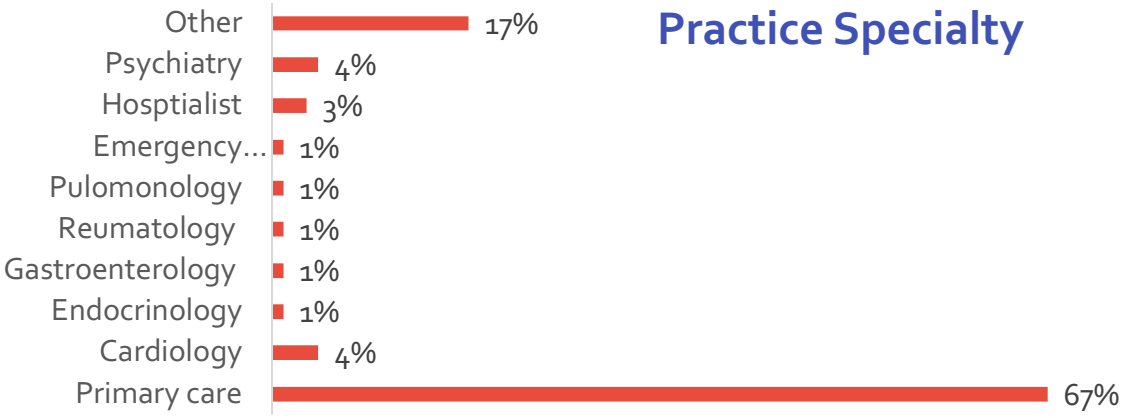
Number of Providers in Your Practice



Number of Patients Seen Each Week



Practice Specialty



RealCME

NACE

Level 2: Satisfaction

- **99%** rated the activity as excellent
- **99%** indicated the activity improved their knowledge
- **97%** stated that they learned new and useful strategies for patient care
- **90%** said they would implement new strategies that they learned
- **99%** said the program was fair-balanced and unbiased

Level 3-5:
Outcomes Metrics

Learner Performance Summary

Pre/Post Test Comparative Analysis Summary

#	Learning Objective (*N* = 2,707)	Pre-Test	Post-Test	% Change
1	Describe the role of the kidney in glucose metabolism in health and disease	18.77%	51.20%	**172.78%***
2	Review the physiologic effects and clinical efficacy of SGLT-2 therapy in various patient populations	60.74%	72.94%	**20.09%***
3	Review emerging data on possible renal and macrovascular effects of evidence-based diabetes treatment options	60.42%	74.71%	**23.65%***
4	Integrate the impact of treatment decisions on postprandial hyperglycemia and risk of hypoglycemia	60.42%	74.71%	**23.65%***

Domain (*N* = 2,707)	Pre-Test	Post-Test	% Change
Knowledge	40.38%	59.83%	**48.17%***
Competence	69.58%	79.85%	**14.76%***
Confidence	2.43	3.54	**45.68%***
Practice Strategy	3.55	3.96	**11.55%***
RealIndex	59.46%	74.37%	**25.08%***

4 Week Post Curriculum Assessment Summary

#	Learning Objective Follow-Up (*N* = 141)	Pre-Test	PCA	% Net-Change
1	Describe the role of the kidney in glucose metabolism in health and disease	18.18%	50.91%	**180.03%***
2	Review the physiologic effects and clinical efficacy of SGLT-2 therapy in various patient populations	66.06%	77.06%	**16.65%**
3	Review emerging data on possible renal and macrovascular effects of evidence-based diabetes treatment options	64.90%	69.32	**6.81%***
4	Integrate the impact of treatment decisions on postprandial hyperglycemia and risk of hypoglycemia	64.90%	69.32%	**6.81%***

Domain Follow-Up (*N* = 141)	Pre-Test	PCA	% Net-Change
Knowledge	42.21%	61.89%	**46.62%***
Competence	77.06%	79.82%	**3.58%**
Confidence	2.34	2.93	**25.21%***
Practice Strategy	3.72	3.39	**-8.87%***
RealIndex	63.10%	68.09%	**7.91%**

* Results are statistically significant $p < .05$

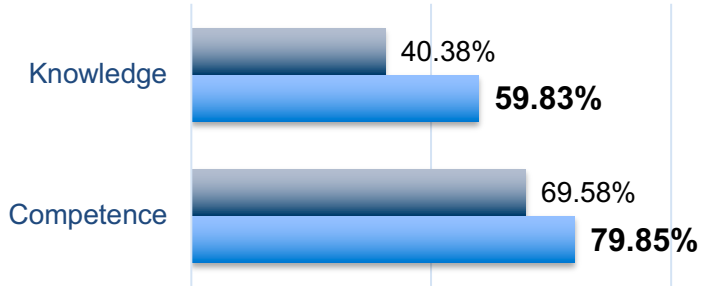
Learning Objectives Analysis

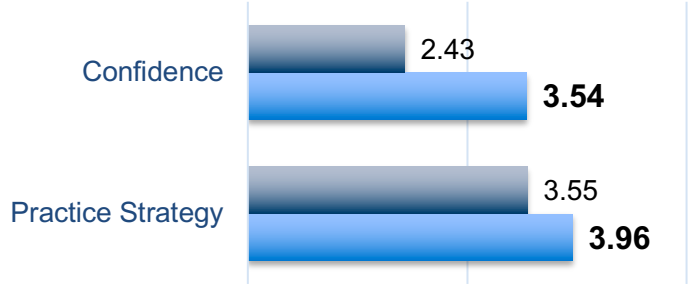
#	Learning Objective (*N* = 2,707)	Pre-Test (SD)	Post-Test (SD)	% Change	*P* Value
1	Describe the role of the kidney in glucose metabolism in health and disease	18.77% (39.06)	51.205 (50.02)	**172.78%**	.000
2	Review the physiologic effects and clinical efficacy of SGLT-2 therapy in various patient populations	60.74% (48.85)	72.94% (44.44)	**20.09%**	.000
3	Review emerging data on possible renal and macrovascular effects of evidence-based diabetes treatment options	60.42% (26.57)	74.71% (24.83)	**23.65%**	.000
4	Integrate the impact of treatment decisions on postprandial hyperglycemia and risk of hypoglycemia	60.42% (26.57)	74.71% (24.83)	**23.65%**	.000

- Significant ($p < .000$) and substantial gains, ranging from 20% to 173%, were measured for all items mapped to curriculum Learning Objectives (LOs). Varied performance remained at the conclusion of the curriculum with learners demonstrating: proficiency on LOs 2, 3 & 4, and ongoing challenge on LO1.
- The greatest gain was observed in LO 1 (197%), however learner's averages on items addressing the role of the kidney in glucose metabolism remained the lowest measured across the curriculum. This finding indicates that while learners improved, persistent gaps in this clinical area remain.
- Standard deviations (SDs) improved to lower levels on all curriculum metrics except LO1 where learner score variance remained elevated.

Learning Domain Analysis

Outcome Indicator (*N* = 2,707)	Pre-Test (SD)	Post-Test (SD)	% Change	*P* Value
Knowledge	40.38% (37.53)	59.83% (38.49)	**48.17%**	< .05
Competence	69.58% (46.02)	79.85% (40.12)	**14.76%**	< .05
Confidence	2.43 (1.17)	3.54 (.98)	**45.68%**	< .05
Practice	3.55 (1.23)	3.96 (1.17)	**11.55%**	< .05





- Statistically significant and substantial improvements were measured across the curriculum in all domains (p < .000). Unlike Knowledge, where the Pre-Test average was low, learners demonstrated greater comparative proficiency in Competence across the curriculum.
- Increases in learners' self reported Confidence and Practice Strategy ratings reflect the efficacy of this education; however, relatively low Post-Test averages in Knowledge demonstrate that this population's perceived and demonstrated proficiency are aligned.
- Standard deviations (SDs), remained elevated at Post-Test in Knowledge and Competence.

The RealIndex Question

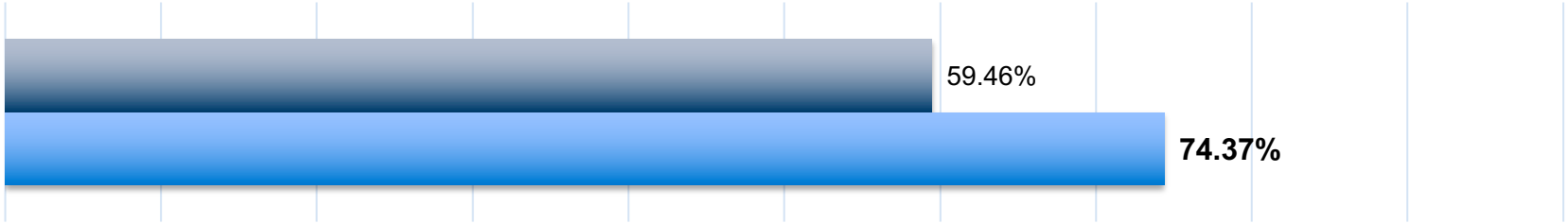
In order to help us assess your baseline knowledge of select topics that will be covered in this activity, please review the brief patient scenario and rate each of the statements as consistent with or inconsistent with your clinical approach.

A 57-year-old obese man with a history of type 2 diabetes, hypertension, reduced renal function (eGFR 55 mL/min/1.73m2), and prior NSTEMI presents for a checkup. His A1C today is 8.1% and average FPG over last two weeks, ~130 mg/dL. Current medications include metformin 1000 mg bid, glipizide 10 mg qd, basal insulin 60 U qam, lisinopril 20 mg qd, atorvastatin 80 mg qd, metoprolol 100 mg bid, and aspirin 81 mg qd. After reviewing the brief scenario above, please rate each of the statements as consistent with or not consistent with best clinical practice:

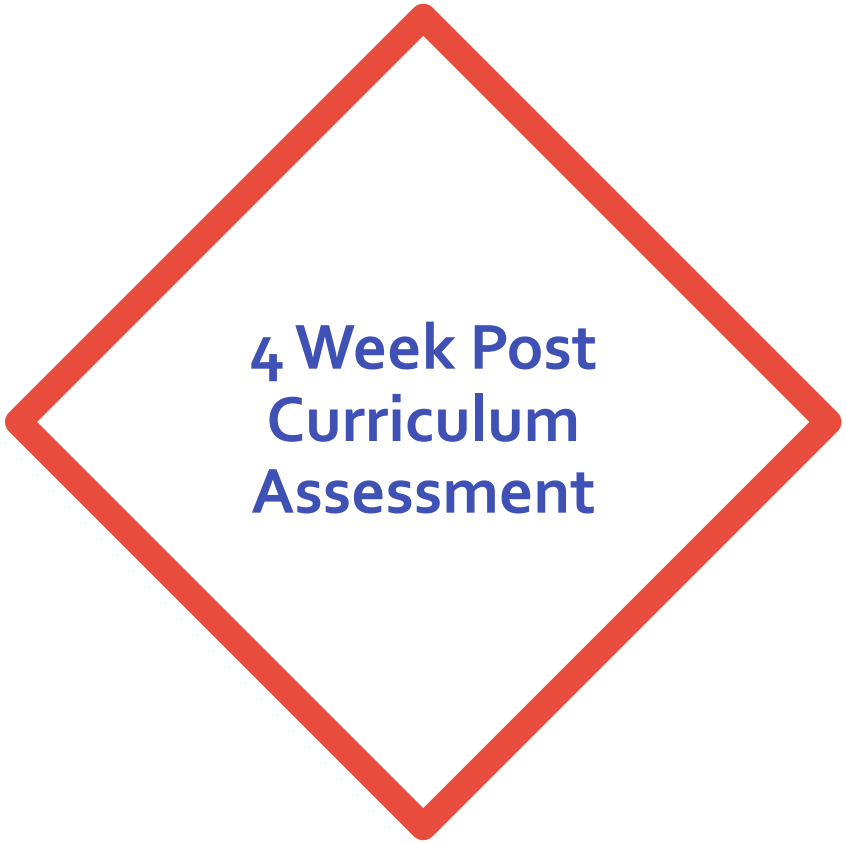
Consistent	Not Consistent
• Discontinue sulfonylurea and add canagliflozin or empagliflozin	• Avoid all SGLT-2 inhibitors based on eGFR <60 mL/min/1.73m2
• If canagliflozin started, limit dose to 100 mg qd	• Add prandial insulin tid and maintain current antidiabetic regimen
	• Increase dose of basal insulin and add DPP-4 inhibitor

Performance Change: RealIndex

Curriculum Intervention					Intervention Effect		
N	Baseline (SD)	Final (SD)	% Change	*P* - Value	Average Effect Size	% Non-Overlap Baseline - Final	Power
2,707	59.46% (27.47)	74.37% (25.74)	**25.08%**	< .05	.559	36.19	1.00



- Participants' average Performance score, based on the RealIndex, improved by 25% from baseline (59%) to final intervention (74%). This substantial improvement in learners' applied clinical proficiency met statistical significance (p < .000) and exceeded the historical RealCME benchmark (5%).
- This curriculum had a medium effect (d = .559) and achieved a high degree of power (1.00), reflected in the magnitude of impact on this population of learners: the 36% non-overlap between the RealIndex distributions measured at baseline and in learners final intervention.
- Standard deviations improved modestly from baseline indicating a moderate amount of score scatter affecting learners' final RealIndex average.


4 Week Post
Curriculum
Assessment

Learning Objectives: Retention

#	Learning Objective (*N* = 141)	Pre-Test (SD)	PCA (SD)	% Change	*P* Value
1	Describe the role of the kidney in glucose metabolism in health and disease	18.18% (38.75)	50.91% (50.22)	**180.03%**	< .05
2	Review the physiologic effects and clinical efficacy of SGLT-2 therapy in various patient populations	66.06% (47.57)	77.06% (42.24)	**16.65%**	.057
3	Review emerging data on possible renal and macrovascular effects of evidence-based diabetes treatment options	64.90% (23.05)	69.32% (23.93)	**6.81%**	.090
4	Integrate the impact of treatment decisions on postprandial hyperglycemia and risk of hypoglycemia	64.90% (23.05)	69.32% (23.93)	**6.81%**	.090

- Net gains, ranging from 7% to 180%, were measured for all items mapped to curriculum Learning Objectives (LOs).
- Varied performance remained at the conclusion of the curriculum with learners demonstrating: proficiency on LOs 2, 3 & 4, and ongoing challenge on LO1.
- The greatest gain was observed in LO 1 (180%), however learner's averages on items addressing the role of the kidney in glucose metabolism remained the lowest measured at follow-up. This finding indicates that while learners retained the majority of their improvement, gaps in this clinical area remain.

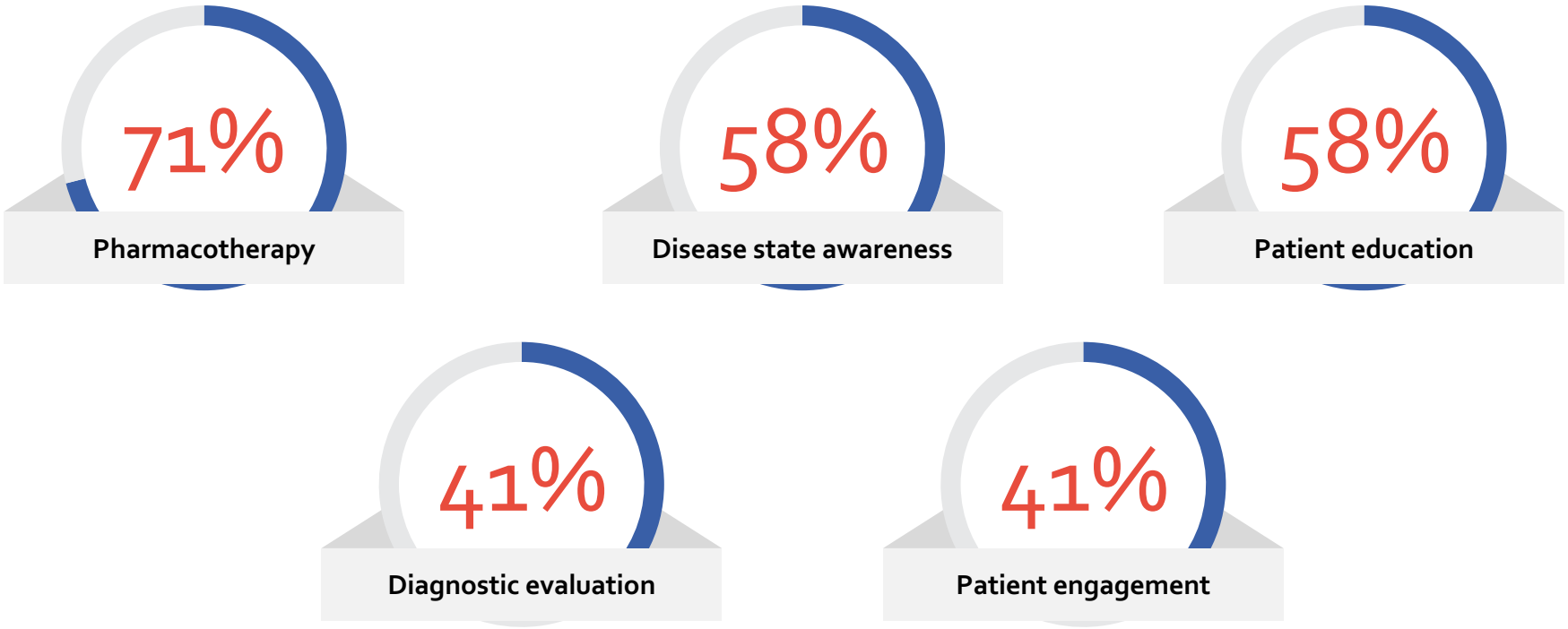
Learning Domain Summary: Retention

Outcome Indicator (*N* = 141)	Pre-Test (SD)	PCA (SD)	% Change	*P* Value
Knowledge	42.21% (36.94)	61.89% (35.82)	**46.62%**	< .05
Competence	77.06% (42.24)	79.82% (40.32)	**3.58%**	.592
Confidence	2.34 (1.16)	2.93 (.99)	**25.21%**	< .05
Practice	3.72 (1.12)	3.39 (1.25)	**-8.87**	.005
RealIndex	63.10% (24.15)	68.09% (23.39)	**7.91**	.069

- Statistically significant and substantial net-improvements were measured at follow-up in Knowledge and Confidence.
- A 9% net decrease was observed in Practice Strategy and a non-significant 8% improvement from baseline was observed at follow-up.

Please select the specific areas of skills, or practice behaviors, you have improved regarding the treatment of patients with type 2 diabetes since this CME activity. (Select all that apply)

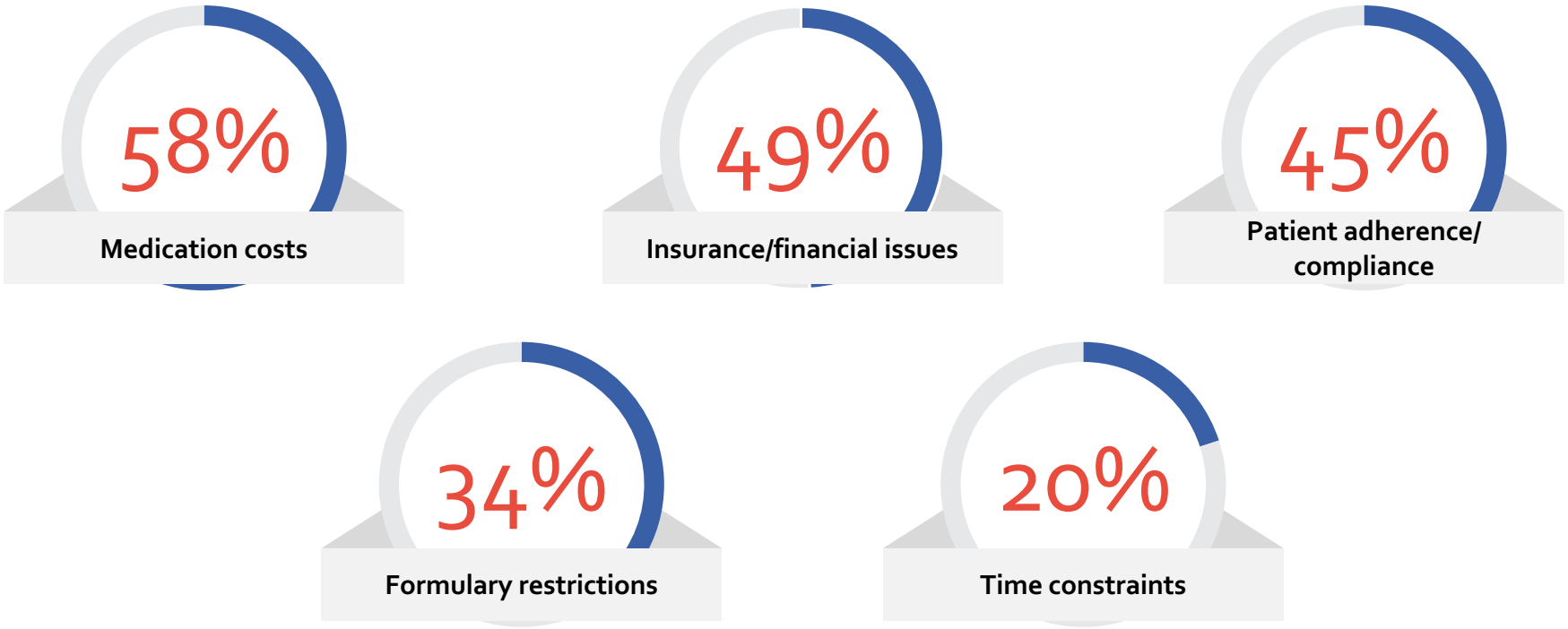
(4-week Post Assessment)



Sample Size: N = 475

What specific barriers have you encountered that may have prevented you from successfully implementing strategies for patients with type 2 diabetes since this CME activity? (Select all that apply)

(4-week Post Assessment)



Sample Size: N = 475

Analysis

Item and Statement-level Analyses

Item and statement-level analyses of all curriculum questions revealed ongoing areas of educational need:

- **Performance** Behavior related to treatment intensification.
  - On the RealIndex, learners were presented with a patient scenario and asked to sort the presented behaviors as consistent or not consistent with their current practice approach. Learners incorrectly endorsed (as "consistent" with their current practice approach):
    - Adding a prandial insulin while otherwise maintaining the patient's current regimen, and
    - Increasing the dose of basal insulin and adding a DDP-4 inhibitor.

- **Knowledge** related to the role of SGLT-2 and GLUT-2. Specifically, 43% of learners underestimated the amount of glucose reabsorption by the kidney mediated by SGLT-2 and GLUT-2 transporters.

- Though gaps in two distinct clinical areas were observed, learners incorrectly endorsed the majority of "not consistent" RealIndex statements relating to treatment intensification.

Summary of Outcomes Analysis: Levels 1-5

- Statistically significant and substantial improvements were measured across the curriculum in all learning domains. The improvements in Knowledge, Competence, and the RealIndex were notable and exceeded historical benchmarks for change established through RealCME meta-analyses.

- An evaluation of self-reported Confidence and Practice Strategy items revealed that, while ratings at Pre-Test were relatively low, robust improvements were achieved by the conclusion of the education.
  - This finding demonstrates that following participation, clinicians felt more able and empowered to make changes in their practice behavior.
  - This finding is reflected in learners' substantial (25%) improvement in Performance.

- This curriculum successfully engaged learners and improved their proficiency. However, persistent gaps remained at the conclusion of the education.
  - Learners were challenged by treatment intensification as well as the role of the kidney in glucose reabsorption
  - There is need for ongoing educational emphasis on SGLT2 inhibitor efficacy
  - There is need for ongoing educational emphasis on role of the kidneys in glucose metabolism.